

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 380 315 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:

14.01.2004 Bulletin 2004/03

(51) Int Cl.7: **A61M 5/32, A61B 5/15**

(21) Application number: **03012190.9**

(22) Date of filing: **04.06.2003**

(84) Designated Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
HU IE IT LI LU MC NL PT RO SE SI SK TR

Designated Extension States:

AL LT LV MK

(30) Priority: **12.06.2002 US 170318**

14.06.2002 US 173239

(71) Applicant: **Becton, Dickinson and Company**
Franklin Lakes, New Jersey 07417-1880 (US)

(72) Inventors:

- **MacLean Crawford, Jamieson William**
New York, NY 10025 (US)
- **Bennett, Michael**
Summit, New Jersey 07901 (US)
- **Newby, C. Mark**
Tuxedo, NY 10987 (US)

(74) Representative: **Müller-Boré & Partner**
Patentanwälte
Grafinger Strasse 2
81671 München (DE)

(54) **Safety needle assembly**

(57) The present invention is a safety shield assembly having a shield and a collar for connecting the shield to a fluid handling device whereby the shield may be pivoted with respect to the collar. Preferably, the safety shield assembly may be used with a needle assembly,

an intravenous infusion set a syringe, a catheter or other fluid handling devices or assemblies that contain piercing elements. The shield includes a clip with a plurality of cannula finger locks for preventing re-exposure of the used needle.

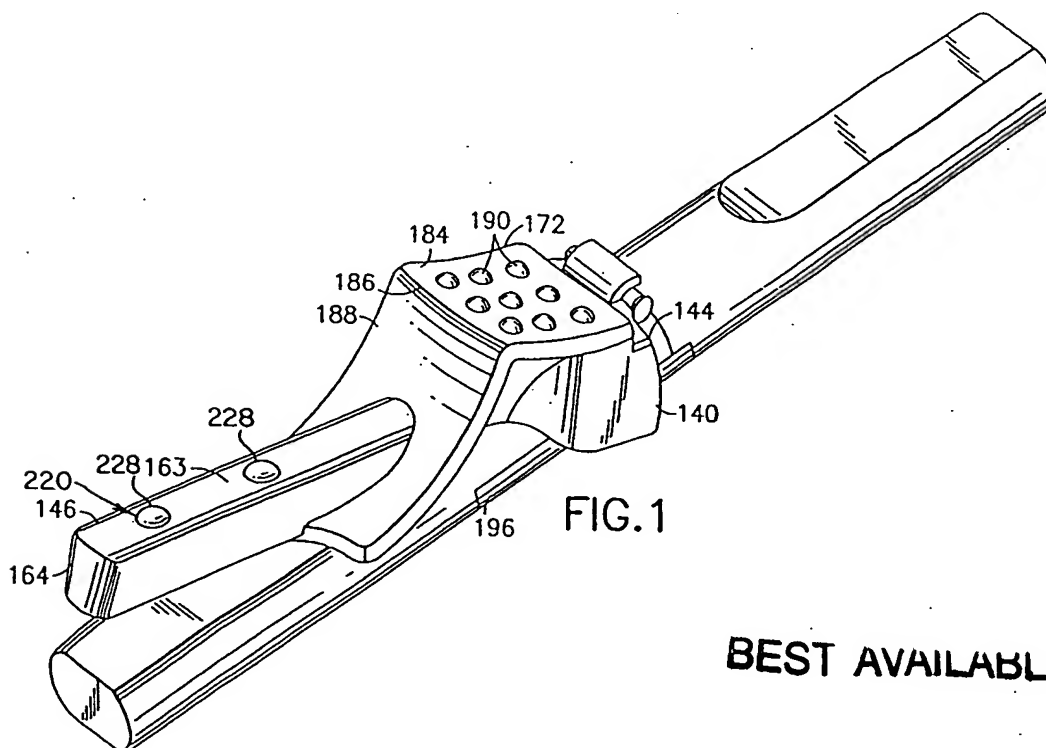


FIG. 1

BEST AVAILABLE COPY

Description

FIELD OF THE INVENTION

[0001] The present invention relates to a shield for a needle and more particularly to a safety shield assembly that may be used in conjunction with a syringe assembly, a hypodermic needle, a needle assembly, a needle assembly with a needle holder, a blood collection needle, a blood collection set, an intravenous infusion set or other fluid handling devices or assemblies that contain piercing elements.

BACKGROUND OF THE INVENTION

[0002] Disposable medical devices having piercing elements for administering a medication or withdrawing a fluid, such as hypodermic needles, blood collecting needles, fluid handling needles and assemblies thereof, require safe and convenient handling. The piercing elements include, for example, pointed needle cannula or blunt ended cannula.

[0003] Safe and convenient handling of disposable medical devices is recognized by those in the medical arts so as to minimize exposure to blood borne pathogens. Safe and convenient handling of disposable medical devices results in the disposal of the medical devices intact.

[0004] As a result of this recognition, numerous devices have been developed for shielding needles after use. Many of these devices are somewhat complex and costly. In addition, many of these devices are cumbersome to use in performing procedures. Furthermore, some of the devices are so specific that they preclude use of the device in certain procedures or with certain devices and/or assemblies. For example, some devices employ very short thin needle cannulas. A shield designed to lock near the distal end of one needle cannula might not engage a much shorter needle cannula. Additionally, a shield designed to lock with a wider gauge needle cannula might be more likely to generate a spray upon engaging a much narrower needle cannula. Furthermore, it may be desirable to reduce the force required to effect shielding without reducing the audible and tactile indications of complete shielding.

[0005] Therefore, there exists a need for a safety shield assembly: (i) that is manufactured easily; (ii) that is applicable to many devices; (iii) that is simple to use with one hand; (iv) that can be disposed of safely; (v) that does not interfere with normal practices of needle use; (vi) that has tactile features whereby the user may be deterred from contacting the needle, the user may easily orient the needle with the patient and easily actuate and engage the shield assembly; (vii) that has visual features whereby the user may be deterred from contacting the needle, the user may easily orient the needle with the patient and easily actuate and engage the shield assembly; (viii) that is not bulky; (ix) that in-

cludes means for minimizing exposure to the user of residual fluid leaking from the needle; and (x) provides minimal exposure to the user because the needle shield is immediately initiated by the user after the needle is withdrawn from the patient's vein.

SUMMARY OF THE INVENTION

[0006] The present invention is a safety shield assembly that comprises: a shield; means for connecting the shield to a fluid handling device that contains a piercing element, such as needle; means for pivoting the shield away from the needle and means for securely covering and/or containing the needle within the shield.

[0007] Preferably, the shield comprises a rearward end, a forward end, a slot or longitudinal opening for housing the used needle in the forward end, means for securing the needle in the slot, means for guiding the needle into the slot, means for connecting the shield and the fluid handling device, means for guiding the user's fingers to move the shield into various positions, and means for retaining the shield securely over the used needle.

[0008] Desirably, the means for connecting the shield to the fluid handling device is a collar. Preferably, the shield is connected movably to a collar which is connected to a fluid handling device.

[0009] Preferably, the shield is connected to the collar by a hanger bar that engages with a hook arm on the collar so that the shield may be pivoted with respect to the collar into several positions. It is within the purview of the present invention to include any structure for connecting the shield to the collar so that the shield may be pivoted with respect to the collar. These structures include known mechanical hinges and various linkages, living hinges, or combinations of hinges and linkages.

[0010] Most preferably, the shield is connected to the collar by an interference fit between the hanger bar and the hook bar. Therefore, the shield always is oriented in a stable position and will not move forward or backwards unless movement of the shield relative to the hanger bar and the hook bar is initiated by the user.

[0011] Alternatively, the shield and collar may be a unitary one-piece structure. The one-piece structure may be obtained by many methods, including molding the shield and the collar as a one-piece unit, thereby eliminating the separate shield and collar during the manufacturing assembly process.

[0012] The assembly of the present invention may further comprise tactile and visual means for deterring the user from contacting the needle, providing easy orientation of the needle with the patient and providing the user with a guide for actuation and engagement with the shield.

[0013] The assembly of the present invention may further comprise means for minimizing exposure by the user to residual fluid leaking from a used needle. For example, a polymer material, such as a gel, may be locat-

ed in the shield.

[0014] Most desirably, the assembly of the present invention is such that the cooperating parts of the assembly provide the means for the shield to move into a forward position over the needle. Thus, by simple movement of the shield into a forward position over the used needle, the assembly is ready for subsequent disposal. Therefore, the safety shield assembly of the present invention provides minimal exposure of the user to a needle because the shielding is initiated by the user immediately after the needle is withdrawn from the patient's vein.

[0015] Desirably, the assembly of the present invention may be used with a syringe assembly, a hypodermic needle, a needle assembly, a needle assembly with a needle holder, a blood collection set, an intravenous infusion set or other fluid handling devices. Preferably, the assembly of the present invention is used with a needle assembly comprising a needle and a hub. Preferably the needle is a conventional double ended needle.

[0016] Most preferably, the present invention is used with a needle assembly comprising a hub and a needle connected to the hub whereby the needle comprises a non-patient end and an intravenous end. The collar of the present invention may comprise a hook arm and the shield may be connected movably to the hook arm. Thus the shield may be pivoted with respect to the collar and moved easily into several positions.

[0017] Preferably, the collar is fitted non-rotatably with the hub of the needle assembly. Additionally, the collar includes cooperating means that mate with reciprocal means on the shield to provide a clear audible and tactile indication of complete shielding. The cooperating means on the collar may include generally chevron-shaped projection formed on a side of the collar substantially diametrically opposite the hook arm or other such structure that provides the hinge connection to the shield. The chevron-shaped structure includes a forward or distal point. Slanting surfaces diverge and extend proximally from the distal point. The slanting surfaces cooperate with the reciprocal means on the shield to generate a deflection of the sidewalls of the shield away from one another. The chevron-shaped structure further includes proximal ends that are convexly arcuate. The convexly arcuate ends of the chevron-shaped structure on the collar cooperate with the reciprocal means on the shield and with the resiliently deflectable sidewalls of the shield to generate the tactile and audible indication of shielding.

[0018] The means for securely locking the shield in the second position comprises a clip secured to the interior of the shield. The clip preferably includes an elongate base with means for attachment to the shield and a plurality cannula finger locks extending from the base for locked engagement with the cannula when the shield is in the second position around the needle cannula. Each cannula finger lock preferably includes a support leg that projects from the base and a cannula engaging

leg or detent that extends from the free end of the support leg. Each cannula finger lock is dimensioned, disposed and aligned to contact the needle cannula when the shield approaches the second position. Contact between the cannula and each cannula finger lock may cause each cannula finger lock and/or the needle cannula to deflect resiliently. Sufficient rotation of the shield will cause the needle cannula to pass the cannula engaging legs. As a result, each cannula finger lock and/or the needle cannula will resiliently return to or toward its undeflected condition for securely trapping the needle cannula in the shield. The means for attaching the clip to the shield may comprise apertures in the shield and snaps or other locking projections formed on the base of the clip. The snaps can be force fit through the apertures in the shield. Alternatively, the means for the clip to the shield may comprise apertures in the clip and snaps or other locking projections formed on the shield. The number and location of the cannula finger locks may be selected in view of the length of the needle. At least two and preferably three cannula finger locks may be provided.

[0019] In an alternate embodiment, the shield preferably includes a proximal or rearward portion that is hingedly connected to the collar and a distal or forward portion that comprises a support extending unitarily from the rearward portion of the shield. The shield may further comprise a cannula channel securely mounted to at least the support of the forward portion. The channel may comprise a top wall securely connected to the support of the shield and a pair of opposed spaced apart sidewalls extending downwardly from the top wall. The spacing between the sidewalls is selected to accommodate the needle cannula in the channel. At least one of the sidewalls of the cannula channel is formed with at least one cannula finger lock that projects angularly toward the top wall of the cannula channel. The cannula finger lock is dimensioned, disposed and aligned to contact the needle cannula when the shield approaches the second position. Contact between the needle cannula and the cannula finger lock will cause the cannula finger lock to resiliently deflect toward the sidewall from which the cannula finger lock extends. Sufficient rotation of the shield will cause the needle cannula to pass the cannula finger lock. As a result, the cannula finger lock will resiliently return to or toward its undeflected condition for securely trapping the needle cannula in the shield.

[0020] The top wall of the cannula channel may comprise means for engaging reciprocal means on the support of the forward portion of the shield. The mounting means on the cannula channel may be disposed in a non-central position relative to the longitudinal direction of the channel. Thus, the cannula channel can be mounted to the shield support in either of two alternate orientations that are rotated 180° from one another. In a first rotational orientation, the cannula channel projects distally or forwardly beyond the support of the shield. In a second rotational orientation, the cannula

channel projects rearwardly or proximally from the support of the shield to overlie the rearward portion of the shield. Thus, the first rotational orientation of the cannula channel ensures that the pointed distal end of a long needle cannula is surrounded by the cannula channel and engaged by the cannula finger locks. The second rotational orientation of the cannula channel ensures that a shorter needle cannula is surrounded by the cannula channel and engaged by the cannula finger locks.

[0021] The cannula channel may have a proximal or rear end configured for engaging the collar or hub when the shield is in its second position. Engagement of the channel with the collar or hub may contribute to locked retention of the shield in the second position. Additionally, engagement of the proximal end of the cannula channel with the collar or hub may further support the channel and prevent excessive deformation of the channel.

[0022] Preferably, the collar is fitted with the hub of the needle assembly so that the collar cannot rotate around the hub. Alternatively, the collar and hub may be a unitary one-piece structure. The one piece structure may be accomplished by many methods including molding the collar and the hub as a one-piece unit thereby eliminating the need to separately assemble the collar to the hub during the manufacturing process.

[0023] Most preferably, the collar is fitted with the hub of the needle assembly so that the bevel surface or bevel up surface of the intravenous or distal end of the needle faces the same side of the collar when the shield is in the first position. Alignment of the collar, hub, shield and needle with the bevel surface up makes it easier to insert the needle into the patient without manipulating the assembly. The orientation of the intravenous end of the needle with the bevel up assures the user that the needle is properly oriented for use and does not require any manipulation before use. Most notably, the orientation of the shield provides a visual indication to the user of the orientation of the bevel surface of the needle.

[0024] Preferably, the shield is capable of pivoting from a first position where the intravenous end of the needle is exposed and bevel up, to an intermediate position where the needle is partially covered, to a second position where the needle is covered completely.

[0025] Alternatively, it is within the purview of the present invention that the shield, collar and hub is a unitary one-piece structure. The one-piece structure may be accomplished by many methods including molding the shield, collar and hub as a one-piece unit thereby eliminating the need to separately assemble the shield, collar and hub during the manufacturing process.

[0026] It is an advantage of the present invention that the shield covering the used intravenous end of the needle provides easy containment of the used needle. A further advantage of the shield is that it will only move upon initiation by the user.

[0027] The assembly of the present invention when

used with a fluid handling device is also easily disposable when removed from a conventional needle holder, or other such device.

[0028] A notable attribute of the present invention is that it is easily adaptable with many devices. For example, the invention is usable with syringe assemblies, hypodermic needles, needle holders, blood collection needles, blood collection sets, intravenous infusion sets such as catheters or other fluid handling devices or assemblies that contain piercing elements.

[0029] Another notable attribute of the present invention is that the tactile and visual features deter the user from touching the needle, allow the user to easily orient the needle with the patient and guide the user to actuate and engage the shield of the assembly.

BRIEF DESCRIPTION OF THE DRAWINGS

[0030] FIG. 1 is a perspective view of the safety shield assembly of the present invention as connected to a needle assembly and related packaging features.

[0031] FIG. 2 is a perspective view of the unassembled pieces of FIG. 1.

[0032] FIG. 3 is a bottom view of the shield as shown in FIG. 2.

[0033] FIG. 4 is a cross sectional view of the collar as shown in FIG. 2 taken along lines 4-4 thereof.

[0034] FIG. 5 is a cross sectional view of the needle hub as shown in FIG. 2 taken along lines 5-5 thereof.

[0035] FIG. 6 is a cross sectional view of the shield of FIG. 2 taken along lines 6-6 thereof.

[0036] FIGS. 7-12 illustrate the use of the safety shield assembly with the needle assembly of FIG. 1 with a conventional needle holder.

[0037] FIG. 13 is a cross sectional view of the assemblies in use with a conventional needle holder as shown in FIG. 12 taken along lines 13-13 thereof.

[0038] FIG. 14 is a cross-sectional view of the assemblies of FIG. 13 taken along lines 14-14 thereof.

[0039] FIG. 15 is a bottom view of the assemblies as shown in FIG. 11.

[0040] FIG. 16 illustrates an additional embodiment of the present invention, whereby a gel material is located in the shield as shown in a bottom view of the assemblies of FIG. 11.

[0041] FIG. 17 is a perspective view of an additional embodiment of the present invention in use with a blood collection set.

[0042] FIG. 18 is a perspective view of an additional embodiment of the present invention in use with a syringe.

[0043] FIG. 19 is a perspective view of an additional embodiment of the present invention in use with a catheter.

[0044] FIG. 20 is a bottom view similar to FIG. 15, but showing an additional embodiment of the present invention.

[0045] FIG. 21 is a perspective view of an alternate

safety shield assembly as connected to a needle assembly and related packaging features.

[0046] FIG. 22 is a perspective view of the unassembled pieces of FIG. 21.

[0047] FIG. 23A is a bottom view of the shield as shown in FIG. 22.

[0048] FIG. 23B is an enlarged bottom view of an ear of the shield.

[0049] FIG. 24A is a cross sectional view of the shield of FIG. 22 taken along lines 24A-24A thereof.

[0050] FIGS. 24B is a cross-sectional view similar to FIG. 24A, but showing the cannula channel in an end-to-end reversed orientation.

[0051] FIG. 25 is a longitudinal cross-sectional view of the assemblies in use with a conventional needle holder.

[0052] FIG. 26 is a cross-sectional view of the assemblies of FIG. 25 taken along lines 26-26 thereof.

[0053] FIG. 27 is an exploded side elevational view of an additional embodiment of the present invention.

[0054] FIG. 28 is a bottom view of the clip of FIG. 27.

DETAILED DESCRIPTION OF THE INVENTION

[0055] While this invention is satisfied by embodiments in many different forms, there is shown in the drawings and will herein be described in detail, the preferred embodiments of the invention, with the understanding that the present disclosure is to be considered as exemplary of the principles of the invention and is not intended to limit the invention to the embodiments illustrated. Various other modifications will be apparent to and readily made by those skilled in the art without departing from the scope and spirit of the invention. The scope of the invention will be measured by the appended claims and their equivalents.

[0056] Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1 and 2 illustrate a needle assembly with the safety shield assembly of the present invention and the related packaging features. The needle assembly includes a needle 40, a hub 60, packaging features to cover the needle and a label. The safety shield assembly includes a collar 90 and a shield 140.

[0057] As shown in FIG. 2 and 5, needle 40 includes a non-patient end 42, an intravenous end 44 and a passageway 46 extending between the non-patient end and the intravenous end. An elastomeric sleeve 48 covers the non-patient end. A first rigid sleeve 50 covers the intravenous end and a second rigid sleeve 52 covers the non-patient end and the elastomeric sleeve. As shown in FIG. 1, a label 196 may also be applied to the finally assembled parts.

[0058] As shown in FIGS. 2 and 5, hub 60 includes a threaded end 64, a ribbed end 66 and passageway 62 extending between the threaded end and the ribbed end. Threaded end 64 and ribbed end 66 are separated by flange 68. Non-patient end 42 of needle 40 extends

from threaded end 64 and intravenous end 44 of needle 40 extends from ribbed end 66. Preferably, threaded end 64 comprises male threads 80 for mounting the hub on a conventional needle holder and ribbed end 66 comprises male ribs 82 for connecting the hub and collar 90.

[0059] As shown in FIGS. 2 and 4, collar 90 includes a forward skirt 92 and a rearward skirt 94. Forward skirt 92 is cylindrical and comprises an inner circumferential surface 96 and an outer circumferential surface 98. Forward skirt 92 mates with rearward skirt 94 at a shoulder 100. Rearward skirt 94 is cylindrical and comprises an inner-circumferential surface 102 and an outer circumferential surface 104 and extends from shoulder 100 opposite of forward skirt 92. The inner diameter of forward skirt 92 is larger than the inner diameter of rearward skirt 94. Alternatively, the inner diameters for collar 90 can be equal. A hook 114 extends from outer circumferential surface 98 of forward skirt 92. Additionally a chevron-shaped protrusion 118 projects outwardly from outer circumferential surface 98 of forward skirt 92 at a side opposite hook 114. The chevron-shape protrusion 118 is substantially symmetrical and has a peak 120 pointed toward forward skirt 92 and ramp surfaces 122 that diverge symmetrically from peak 120 toward rearward skirt 94. Ramp surfaces 122 terminate at rounded ends 124 at the outer side and proximal extremes of chevron-shaped protrusion 118. Rounded ends 124 extend continuously into the proximal side of chevron-shaped protrusion 118 facing toward rearward skirt 94.

[0060] As shown in FIGS. 2 and 6, shield 140 comprises a rearward end 144 and a forward end 146. Forward end 146 of shield 140 includes a slot or longitudinal opening 160 formed by sidewalls 162 that extend downwardly from top wall 163 and run substantially opposite of one another in parallel along the length of slot 160 towards forward end wall 164. Slot 160 is slightly wider than needle 40. Sidewalls 162 include bottom edges 165 that extend substantially parallel to one another and parallel to top wall 163. Top wall 163 is formed to include two longitudinally spaced apertures 167 extending entirely therethrough.

[0061] Shield 140 further includes a clip 220. Clip 220 includes an elongate base 222 having a width less than the distance between sidewalls 162 at forward end 146 of shield 140. Base 222 includes opposite top and bottom surfaces 224 and 226. Top surface 224 is configured to nest closely with the inner surface of top wall 163 of shield 140. Top surface 224 is characterized by mounting projections 228. Mounting projections 228 are disposed and configured to be snap fit through apertures 167 in top wall 163 of shield 140. More particularly, each mounting projection 228 includes a head that is tapered to a cross-sectional dimension slightly greater than the inside cross-sectional dimension of the respective aperture 167 in top wall 163. Thus, the head of mounting projection 228 and portions of top wall 163 adjacent apertures 167 will yield slightly as mounting projections 228 are forced through apertures 167. Top wall

163 and mounting projections 228 will return resiliently to their initial position after the enlarged heads passed through apertures 167. Hence, base 222 of clip 220 will be held securely adjacent top wall 163 of shield 140.

[0062] Clip 220 is characterized further by a plurality of cannula finger locks 230a, 230b and 230c projecting from bottom surface 226 of base 222. Each cannula finger lock 230 includes a support leg 232 and a locking finger 234. Cannula finger locks 230 can take any of several optional constructions. For example, support leg 232 can be substantially rigid with respect to base 222 and locking finger 234 can be substantially rigid with respect to support leg 232. In these situations, cannula finger locks 230 will function to deflect needle 40 resiliently and then to trap needle 40 beneath locking finger 234. Alternatively, the support leg 232 can be resiliently deflectable relative to base 222. Thus, the support leg 232 may deflect relative to base in response to forces generated by contact with needle 40. Support leg 232 then will return resiliently to an undeflected condition so that locking finger 234 engages and traps needle 40. This embodiment requires base 220 to be sufficiently narrow to permit deflection of support leg 232. As a further option, locking finger 234 may be configured to deflect resiliently relative to support leg 232. Still further, both support leg 232 and locking finger 234 may be resiliently deflectable.

[0063] Base 222, as shown most clearly in FIGS. 3 and 6 is longer than top wall 163 of forward end 146 of shield 140. Hence, base 222 includes a distal end 236 near forward end wall 164 and a proximal end 238 that extends into rearward end 144 of shield 140. Cannula finger lock 230a is disposed near proximal end 238 of base 222 and in rearward end 144 of shield 140. As a result, proximal cannula finger lock 230a is particularly useful for needle assemblies that employ a very short needle 40. Of course, however, cannula finger locks 230b and 230c also can be employed in situations where needle 40 is longer.

[0064] Broken line 240 in FIG. 2 shows an optional proximal end for base 222. Base 222 with a proximal end at line 240 can be used with needle assemblies known to employ the long needle 40. In this embodiment, base 222 does not extend into rearward end 144 of shield 140.

[0065] Rearward end 144 of shield 140a is substantially identical to rearward end 144 of shield 140. Thus, a repetitive description is not provided and corresponding elements merely are identified by the same reference numerals.

[0066] The extreme rear ends of sidewalls 174 on collar engaging area 166 include rounded ears 194 that project toward one another from opposed inner surfaces 175 of sidewalls 174. Rounded ears 194 are disposed to engage chevron-shaped projection 118 on collar 90. More particularly, each rounded ear 194 includes a distal surface 195, a proximal surface 197 and a curved surface 198 extending between distal and proximal sur-

faces 195 and 197. Distal surface 194 is aligned to sidewall 174 at a rake angle of approximately 60° and proximal surface 197 is aligned to sidewall 174 at an angle of approximately 45°. Curved surface 198 extends smoothly and convexly between distal and proximal surfaces 195 and 197. Proximal surfaces 197 of rounded ears 194 will engage ramp surfaces 122 of chevron-shaped projection 118 to deflect sidewalls 174 slightly away from one another as shield 140 approaches the second position. The apex of curved surface 198 on each rounded ear 194 passes the respective rounded end surface 124 on chevron-shaped projection 118 on collar 90. As a result, sidewalls 174 begin to return resiliently toward an undeflected condition. The resilient return of sidewalls 174 and raked distal surface 195 of ears 194 also causes sidewalls 174 to snap against chevron-shaped projection 118. This snapping action provides a clear audible and tactile indication of complete shielding and occurs substantially when the used needle is trapped by cannula finger locks 230. The angles of distal and proximal surfaces 195 and 197 of rounded ears 194 affects the performance of shield 140. In particular, a smaller acute angle alignment of proximal face 197 reduces the force required to move shield 140 passed rounded ears 194. A larger acute angle proximal surface 197 of rounded ears 194 requires a greater force to move shield 140 toward the second position. Similarly, the angle between distal surface 195 and sidewall 174 affects the acceleration characteristics as shield 140 is propelled toward the second position in response to the resilient return of sidewalls 174 and hence affects the audible indication of shielding.

[0067] Top finger guide area 172 comprises a first ramp 184 that extends slightly on an upwardly slope from the rearward end of the collar engaging area to a shoulder 186. From shoulder 186 extends a second ramp 188 which slopes downwardly towards top section 163. Most preferably, first ramp 184 comprises touch bumps 190. The touch bumps provide a tactile and visual guide to alert the user that the user's finger has contacted the shield and that the shield is in a defined or controlled position. The touch bumps may be any configuration so long as they extend and are distinct from the top finger guide area. The touch bumps may also be of a distinguishing color as compared to the top finger guide area or the shield.

[0068] Second ramp 188 has interior surface 192 for urging the needle toward the center of slot 160 as the shield is being rotated into the second position. The exterior surfaces are slightly inclined and extending radially from the second ramp. The interior surfaces are especially helpful if the longitudinal axis of the needle is misaligned with respect to the longitudinal axis of the hub.

[0069] Extending arms 180 are located at rearward end 168 and at the beginning of top finger area 172 and hold hanger bar 182.

[0070] The safety shield assembly and the needle as-

sembly are assembled together whereby needle 40 is connected to hub 60 and sealed with adhesive at the ends of the hub. Hub 60 is then joined with collar 90 by ultra-sonic welding techniques or any other bonding techniques, or mechanical fit, whereby rearward annular skirt 94 of collar 90 mates with ribbed end 66 of the hub. Male ribs 82 of the hub are contained or forced fitted within inner sidewall 102 of rearward annular skirt 94 of collar 90. The collar is aligned with the intravenous end of the needle whereby the hook arm is aligned with the bevel up of the needle. Then rigid sleeve 50 is force fitted into inner side wall 96 of forward skirt 92 of collar 90 to cover the needle. Clip 220 is mounted into shield 140 by forcing mounting projections 228 through mounting apertures 167 in shield 140. Thereafter, shield 140 is connected to collar 90 whereby hanger bar 182 is force fitted into hook member 114 whereby slot 160 faces rigid sleeve 50. Most preferably, the shield is connected to the collar by a force fit or interference fit between the hanger bar and the hook bar. Therefore, the shield is always oriented in a stable position and will not move unless movement of the shield is positively initiated by the user. To assemble the last piece, shield 140 is moved towards rigid sleeve 50 and second rigid sleeve 52 is force fitted onto outer sidewall 104 of rearward skirt 94 of collar 90.

[0071] In addition, a label 196 may be applied to the finally assembled parts. The label may be used to provide tamper resistance of the parts, so that they are not reused.

[0072] In use, as shown in FIGS. 7-15, the non-patient needle shield is removed and then a needle holder is screwed onto the hub of the needle. As specifically shown in FIGS. 8 and 12 the shield is then rotated back by the user towards the needle holder. Then as shown in FIG. 9, the intravenous needle shield is removed from covering the intravenous needle. Then as shown in FIG. 10, a venipuncture is conducted whereby the intravenous end of the needle is inserted into a vein of a patient and an evacuated tube having a closure is inserted into the needle holder. Then as shown in FIGS. 11 and 13, when the venipuncture is complete the user easily rotates the shield from the first position towards the intravenous needle to an intermediate position and then the user pushes on the shield at the top finger guide area to move the shield into a second position whereby the needle is trapped in the longitudinal opening. More particularly, needle 40 contacts cannula finger locks 230a-c of clip 220. The engagement of needle 40 with cannula finger locks 230a-c causes cannula finger locks 230a-c to deflect sufficiently to pass needle 40. As a result, cannula finger locks 230a-c will return resiliently to an undeflected condition. Thus, needle 40 will be trapped between cannula finger locks 230a-c and base 222. The deflection of cannula finger locks 230a-c can occur in the support legs 232 and/or the locking fingers 234. Alternatively, cannula finger locks 230a-c can be substantially rigid structures that generate deflection of needle

40 sufficient for needle 40 to pass locking fingers 234. Needle 40 then will return resilient to an undeflected condition and will be trapped between locking fingers 234 and base 222.

[0073] Needle 40 is contained within shield 140 as the shield is pivoted into the second position. More particularly, proximal surfaces 197 of rounded ears 194 move over ramp surfaces 122 of chevron-shaped projection 118 and cause sidewalls 174 to deflect away from one another. The angularly aligned proximal faces 197 of rounded ears 194 ensure easy movement of shield 140. Additionally, the resiliency of sidewalls 174 and the angular alignment of distal surface 195 of ears 194 causes a cooperation with rounded proximal ends 124 of chevron-shaped projection 118 to accelerate shield 140. This accelerated movement of shield 140 helps to generate a clear audible and tactile indication of complete shielding.

[0074] Alternatively as shown in FIG. 16, a gel material 190 is located in shield 140 so that when the needle snaps past cannula finger locks 230 it will come to rest in gel material 190. The gel material will contain any residual fluid that may be on the needle. Simultaneously, rounded ears or projections 198 move over rounded proximal ends 124 of chevron-shaped projection 118. This causes sidewalls 174 to deflect away from one another and then to snap back into engagement with collar 90 to provide a clear audible and tactile indication of complete shielding.

[0075] FIGS. 17, 18, and 19 are further embodiments of the invention that may include components which are substantially identical to the components of FIGS. 1-3. Accordingly, similar components performing similar functions will be numbered identically to those components of FIGS. 1-3, except that a suffix "a" will be used to identify those similar components in FIG. 17, a suffix "b" will be used to identify those similar components in FIG. 18 and a suffix "c" will be used to identify those similar components in FIG. 19.

[0076] Alternatively, the safety shield assembly of the present invention may be used in conjunction with a conventional intravenous (IV) infusion set, as illustrated in FIG. 17.

[0077] For purposes of illustration, shield 140a and collar 90a are connected to a conventional IV infusion set, 200, or butterfly structure comprising a needle body with a needle hub 204 extending from the forward end of the needle body and a needle 206 embedded in hub 204. Extending from the rearward end of the needle body is flexible tubing 208 which is conventional and utilized to allow the user to manipulate the structure and to connect it subsequently to supplies of infusion liquids or for the return of collected blood if the arrangement is being used to collect blood.

[0078] Infusion set 200 further comprises flexible wings 210 attached to and projecting outwardly from needle hub 204.

[0079] Alternatively, the safety shield assembly of the

present invention may be used in conjunction with a syringe, as illustrated in FIG. 18.

[0080] For purposes of illustration, shield 140b and collar 90b are connected to a conventional hypodermic syringe 300 comprising a syringe barrel 302 having a distal end 304 a proximal end 306 and a plunger 312.

[0081] Alternatively, the present invention may be used in conjunction with a catheter as illustrated in FIG. 19.

[0082] A further alternate embodiment is illustrated in FIG. 20, and is virtually identical to the embodiment of the invention depicted in FIG. 15A. As a result, comparable numerals have been employed to identify identical or very similar components. FIG. 20, however, differs from FIG. 15A in that collar 90 does not have the chevron-shaped protrusion 118 illustrated in FIG. 15A. Additionally, shield 140 does not have ears comparable to rounded ears 194 of FIG. 15A. Thus, the embodiment illustrated in FIG. 20 relies entirely upon the engagement of cannula finger locks 220 with needle 40. There are fewer structures on the embodiment of FIG. 20 to achieve the audible and tactile indication of complete shielding, as in the previous embodiment, and no structure for accelerating shield 140 into the second position around needle 40. However, upon complete shielding, the retention between shield 140 and needle 40 in the embodiment of FIG. 20 is comparable to the attention achieved by the previous embodiments.

[0083] FIGS. 21-26 show an alternate shield 140a. Shield 140a comprises a rearward end 144 and a forward end 146a. Forward end 146a of shield 140a defines an elongate support wall 150 with a distal end 152 and top and bottom surfaces 154 and 156 extending proximally from distal end 152. In the illustrated embodiment, top and bottom surfaces 154 and 156 are slightly arcuate from side-to-side. However, in other embodiments, top surface 154 and/or bottom surface 156 may be substantially planar. Support wall 152 is characterized by axially spaced apertures 158 extending entirely therethrough from top surface 154 to bottom surface 156.

[0084] Rearward end 144 of shield 140a is substantially identical to rearward end 144 of shield 140. Thus, a repetitive description is not provided and corresponding elements merely are identified by the same reference numerals.

[0085] Shield 140a further includes a cannula channel 220a. Cannula channel 220a includes opposed longitudinal ends 222a and 224a, an elongate convex outer surface 226a extending between ends 222a and 224a and an inner concave surface 228a extending between ends 222a and 224a. An entry to concave inner surface 228a is defined by opposed parallel edges 230a that extend substantially between ends 222a and 224a of channel 220a. Mounting projections 232a project from convex outer surface 226a at a location substantially equally spaced from edges 230a. Thus, mounting projections 232a are substantially opposite from the entry

into concave inner surface 228a of channel 220a. Mounting projections 232a are spaced from one another by a distance substantially equal to the spacing between mounting apertures 158 in support wall 150. Additionally, mounting projections 232a are dimensioned to be snapped or force fit into apertures 158. Mounting projections 232a are not symmetrically disposed along the length of cannula channel 220a. Rather, mounting projections 232a are closer to end 222a than to end 224a. Channel 220a is defined further by cannula finger locks 234a that project obliquely inwardly from one of side edges 230a. Cannula finger locks 234a are resiliently deflectable in response to forces exerted by needle 40 as explained further below.

[0086] As shown in FIGS. 22, 23A and 24A, channel 220a can be oriented such that end 224a of channel 220a projects distally or forwardly beyond support wall 150. This orientation is appropriate in situations where it is known that a relatively long needle cannula will be employed with the needle assembly. Alternatively, however, channel 220a can be oriented as shown in FIG. 24B so that end 222a of channel 220a is aligned substantially with the distal end 152 of support wall 152 while end 224a of channel 222a projects rearwardly or proximally into rearward end 144 of shield 140a.

[0087] Shield 140a is used substantially in the same manner as shield 140 described above and illustrated in FIGS. 7-15. More particularly, needle 40 contacts cannula finger locks 234a. Accordingly, cannula finger locks 234a deflect toward support wall 150 and away from edges 230a. Sufficient rotation of shield 140 will cause needle 40 to pass cannula finger locks 234a. As a result, cannula finger locks 234a will return resiliently to an undeflected condition. Thus, needle 40 will be trapped above cannula finger locks 234a.

[0088] Needle 40 is contained within shield 140a as the shield is pivoted into the closed position. More particularly, proximal surfaces 197 of rounded ears 194 move over ramp surfaces 122 of chevron-shaped projection 118 and cause sidewalls 174 to deflect away from one another. The angularly aligned proximal faces 197 of rounded ears 194 ensure easy movement of shield 140a. Additionally, the resiliency of sidewalls 174 and the angular alignment of distal surface 195 of ears 194 causes a cooperation with rounded proximal ends 124 of chevron-shaped projection 118 to accelerate shield 140a. This accelerated movement of shield 140a helps to generate a clear audible and tactile indication of complete shielding.

[0089] FIGS. 27 and 28 show a further alternate to the needle assemblies described and illustrated above. In particular, the embodiment of FIGS. 27 and 28 includes a shield 140d that is similar to the shield 140a described and illustrated above. Shield 140d includes a collar engaging area 166d with a top finger guide area 172d and sidewalls 174d that extend downwardly from top finger guide area 172d. Sidewalls 174d differ from the embodiments described and illustrated above in that they ex-

tend a shorter distance from top finger guide area 172d and have no means for engaging the chevron-shaped projection on the collar.

[0090] Shield 140d includes a forward end 146d with a top wall 163d and sidewalls 162d extending down from top wall 163d. Top wall 163d is characterized by spaced apart mounting apertures 164d.

[0091] Shield 140d further includes a channel-shaped clip 220d having a proximal end 222d, a distal end 224d and a top wall 226d extending from distal end 224d toward proximal end 222d. The top wall includes a pair of spaced apart mounting projections 228d that are dimensioned to be mounted in mounting apertures 158d on forward end 146d of shield 140d. Cannula finger locks 230d extend from the channel-shaped clip in a direction away from mounting projections 228d. Each cannula finger lock 230d includes a support leg and a cannula engaging leg 234d. Cannula finger locks 230d are dimensioned and configured to trap the needle cannula when shield 140d is rotated into the closed position.

[0092] Proximal end 222d of clip 220d includes a pair of collar engaging legs 236d extending generally proximally from top wall 226d. Cannula engaging legs 236d are configured to pass around opposite respective sides of the collar. Ends of collar engaging legs 236d furthest from top wall 226d are formed with rounded ears 238d. Ears 238d are configured to snap into engagement with the chevron-shaped projection, as described above.

[0093] Shield 140d is used substantially exactly as shield 140 described above. In particular, shield 140d can be rotated from the open position to the closed position. As shield 140d approaches the closed position, cannula engaging legs 234d of cannula locking fingers locks 230d engage the needle cannula. Simultaneously, rounded ears 238d engage the chevron-shaped projection. The rounded configuration of ears 238d helps to propel shield 140d toward the closed position. In the closed position, cannula finger locks 230d will snap past the needle cannula for permanently trapping the needle cannula within shield 140d.

[0094] The shield and collar of the safety shield assembly of the present invention are comprised of moldable parts which can be mass produced from a variety of materials including, for example, polyethylene, polyvinyl chloride, polystyrene or polyethylene and the like. Materials will be selected which will provide the proper covering and support for the structure of the invention in its use, but which will provide also a degree of resiliency for the purpose of providing the cooperative movement relative to the shield and the collar of the assembly.

Claims

1. A safety needle assembly comprising a needle hub with proximal and distal ends and a passage extending between said ends, a needle cannula mounted to said passage of said needle hub and

having a pointed distal end projecting beyond said distal end of said hub, a shield having proximal and distal ends, said proximal end of said shield being hingedly mounted to said hub for rotation from a first position where said shield is spaced from said needle cannula to a second position where said shield substantially shields said needle cannula, said shield comprising at least one support wall, a locking structure mounted to said support wall, said locking structure having a top wall and at least one resiliently deflectable cannula finger lock, said cannula finger lock engaging said needle cannula when said shield is rotated to said second position.

2. The safety needle assembly of claim 1, wherein said top wall of said locking structure comprises mounting members for mounting said locking structure to said support wall, said locking structure having opposite first and second longitudinal ends, said mounting members being closer to said first end of said locking structure than to said second end, whereby said locking structure can be disposed in either a first rotational orientation or in a second rotational orientation relative to said support wall for altering positions of said locking structure relative to said needle cannula.
3. The safety needle assembly of claim 2, wherein said support wall has a distal end remote from said proximal end of said shield, said locking structure being dimensioned such that in said second rotational orientation of said locking structure relative to said support wall, said second end of said locking structure projects distally beyond said distal end of said support wall.
4. The safety needle assembly of claim 3, wherein said locking structure is dimensioned such that in said first rotational orientation, said first end of said locking structure substantially aligns with said distal end of said support wall.
5. The needle assembly of any of claims 2-4, wherein said locking structure is dimensioned such that in said first rotational orientation, said second end of said locking structure is substantially adjacent said proximal end of said shield.
6. The safety needle assembly of any of claims 2-5, wherein said at least one cannula finger lock comprises a plurality of cannula finger locks, a first of said cannula finger locks being substantially adjacent said first end of said locking structure and a second of said cannula finger locks being substantially adjacent said second end of said locking structure.
7. The safety needle assembly of any of claims 1-6,

wherein said support wall has a concave surface configured for closely receiving said locking structure.

said shield is rotated into said second position and as said rounded ears move over said rounded proximal ends of said chevron-shaped projection.

8. The safety needle assembly of any of claims 1-7, wherein the locking structure is a locking channel having first and second sidewalls extending from said top wall. 5
9. The safety needle assembly of any of claims 1-8, wherein said support wall comprises a plurality of apertures extending therethrough, said locking structure having a plurality of mounting projections formed thereon, said mounting projections being dimensioned and disposed for locked engagement with said apertures in said support wall. 10 15
10. The safety needle assembly of any of claims 1-9, wherein portions of said shield adjacent said proximal end are configured for partly surrounding said hub, said support wall extending substantially rigidly from said portions of said shield dimensioned for partly surrounding said hub. 20
11. The safety needle assembly of any of claims 1-7, wherein said shield comprises first and second sidewalls extending unitarily from said support wall, said locking structure defining a clip mounted to said support wall and between said sidewalls of said shield. 25 30
12. The safety needle assembly of claim 11, further comprising at least one support leg extending from said top wall of said clip, said cannula finger lock projecting from an end of said support leg remote from said top wall of said clip. 35
13. The safety needle assembly of any of claims 1-12, further comprising a chevron-shaped projection formed externally on said hub, and preferably at a location on said hub substantially opposite said hinged connection of said shield to said hub, said chevron-shaped projection including a central point facing distally on said hub and a pair of rounded ends facing proximally on said hub, rounded ears formed on said shield for engaging said rounded proximal ends of said chevron-shaped projection when said shield is in said second position, whereby said rounded ears and said rounded proximal ends of said chevron-shaped projection provide audible and tactile indication of said shield reaching said second position. 40 45 50
14. The safety needle assembly of claim 13, wherein said rounded ears are formed on inwardly facing surfaces of said sidewalls of said shield, and wherein said rounded ears are dimensioned to require deflection of said sidewalls away from one another as 55
15. The safety needle assembly of any of claims 13-16, wherein each said rounded ear comprises a proximal face aligned to said respective sidewall at an acute angle, a distal face aligned to said respective side wall at an acute angle of preferably about 60° and a curved surface extending between said proximal and distal faces.

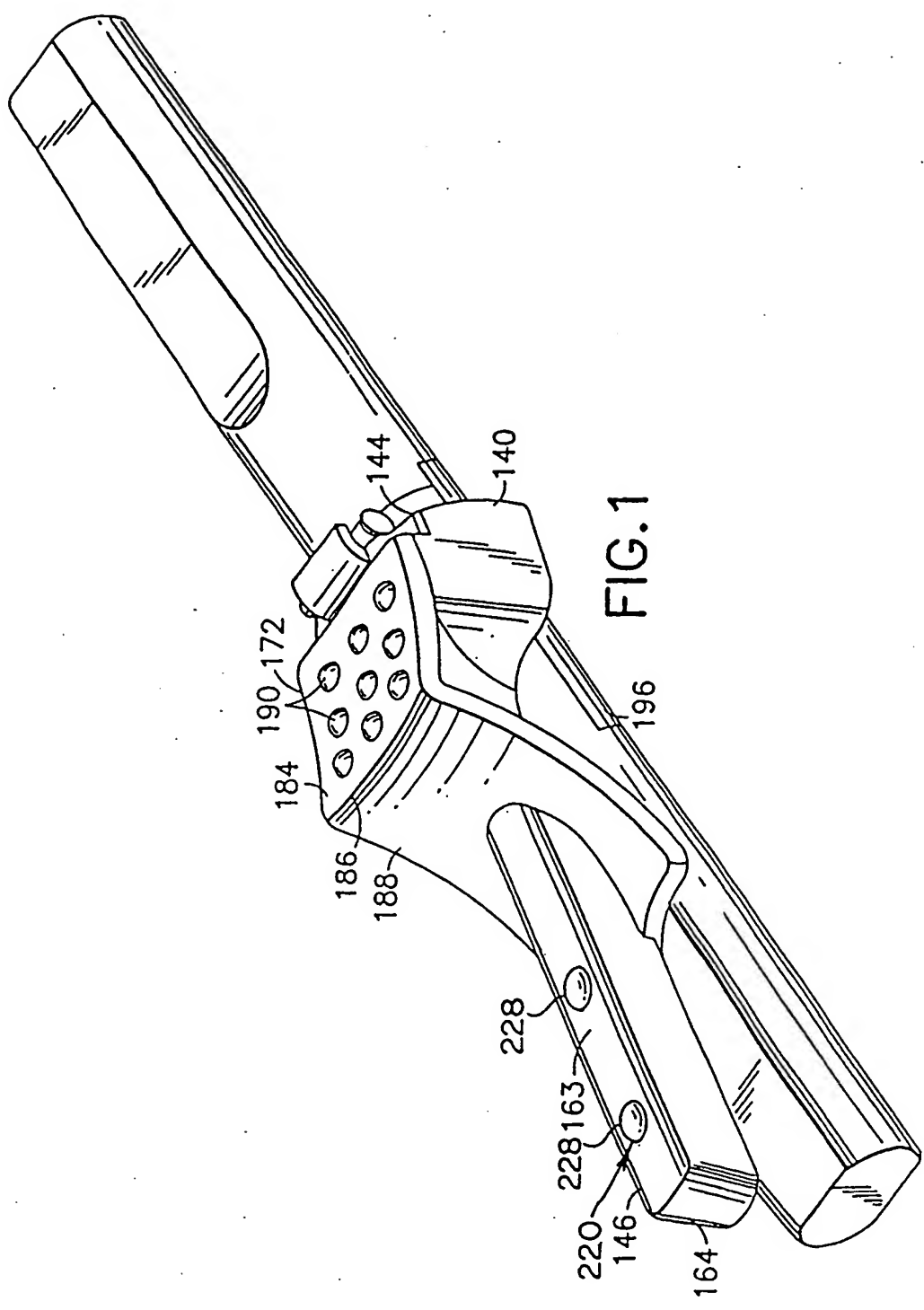
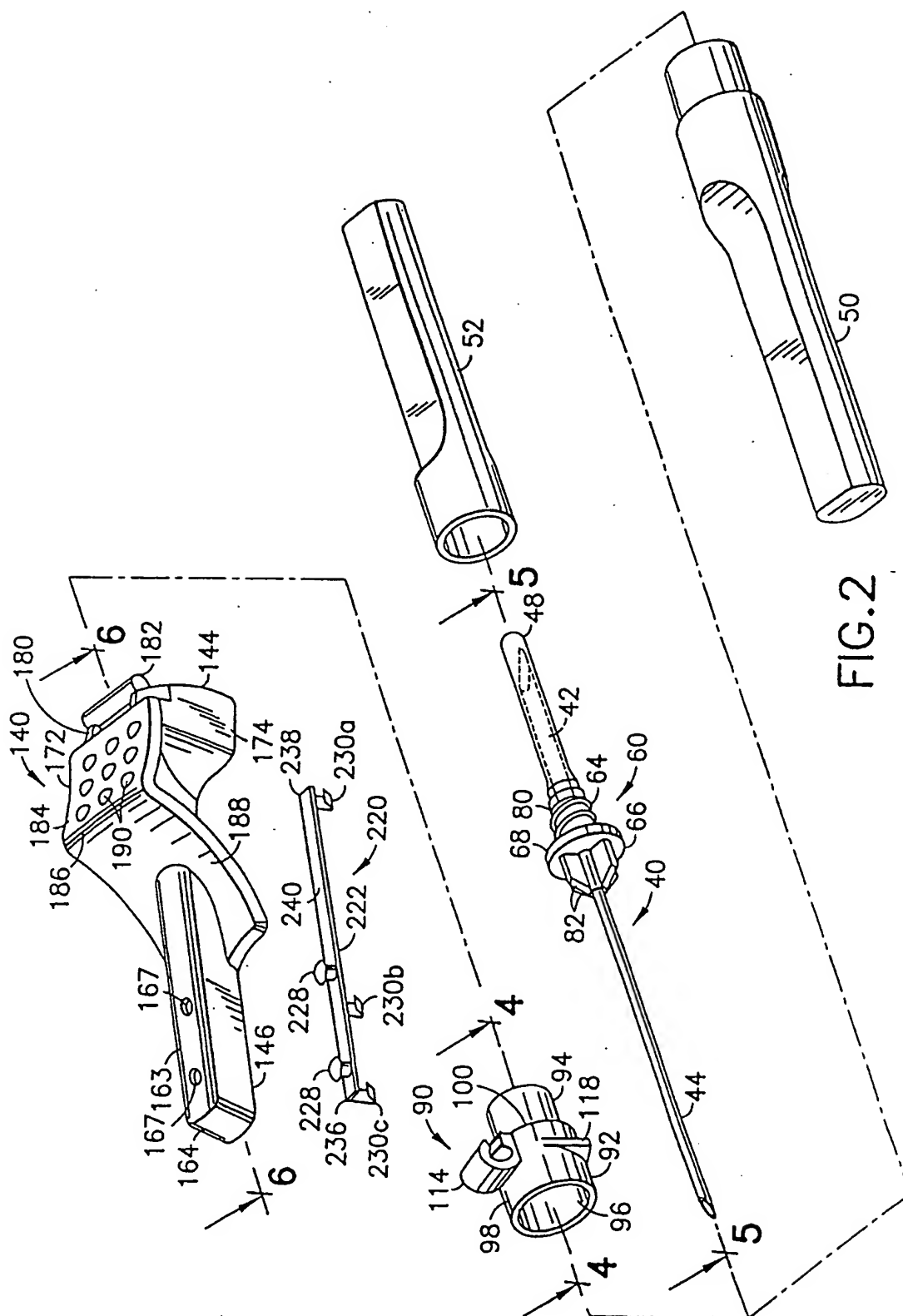
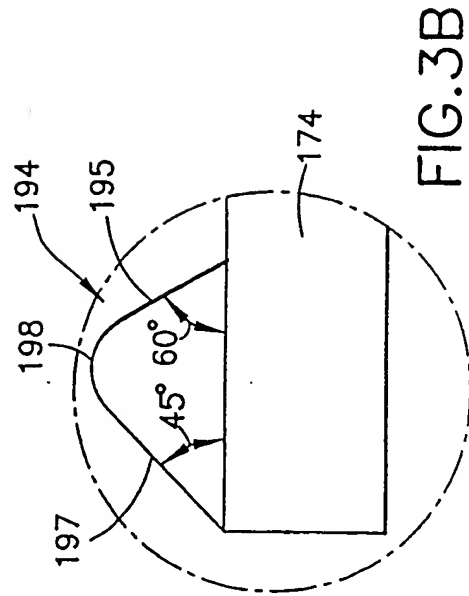
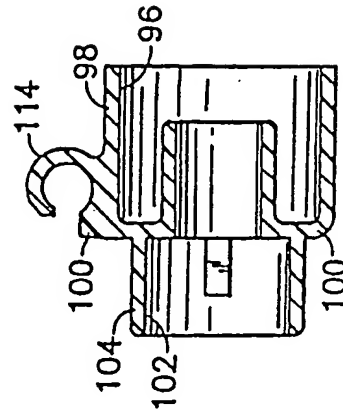
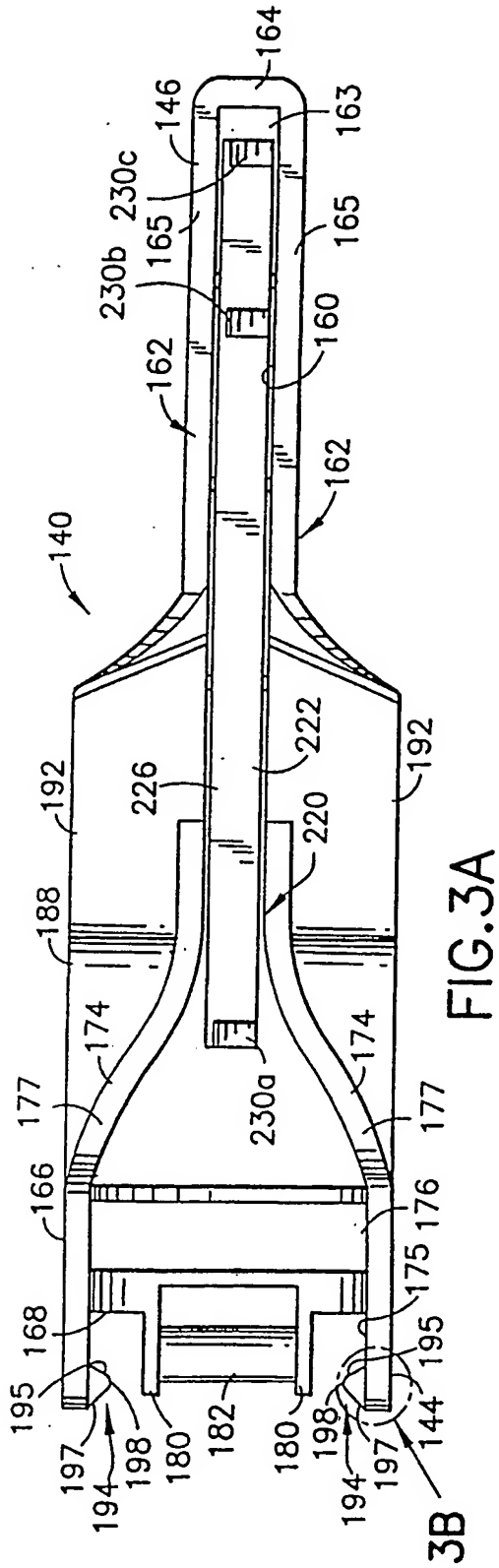
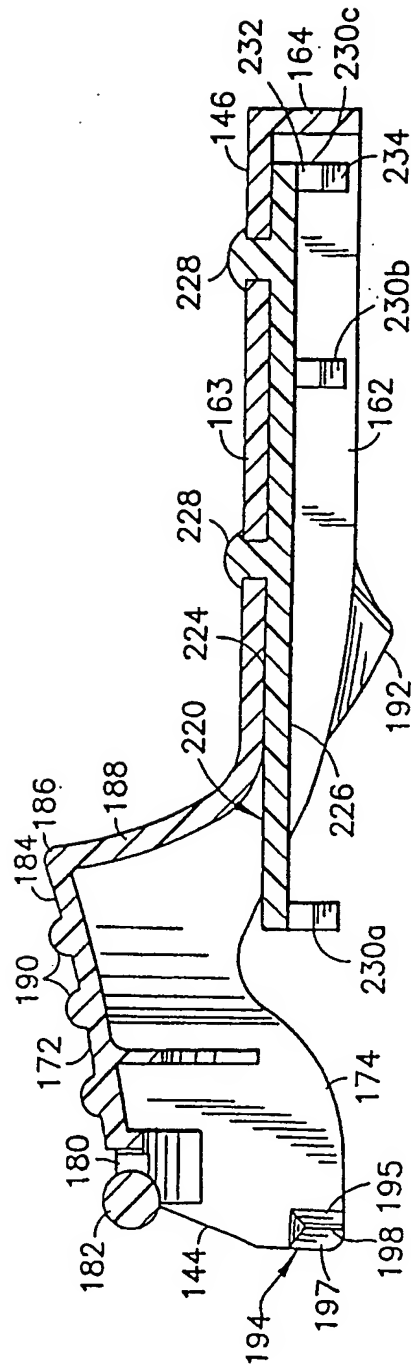
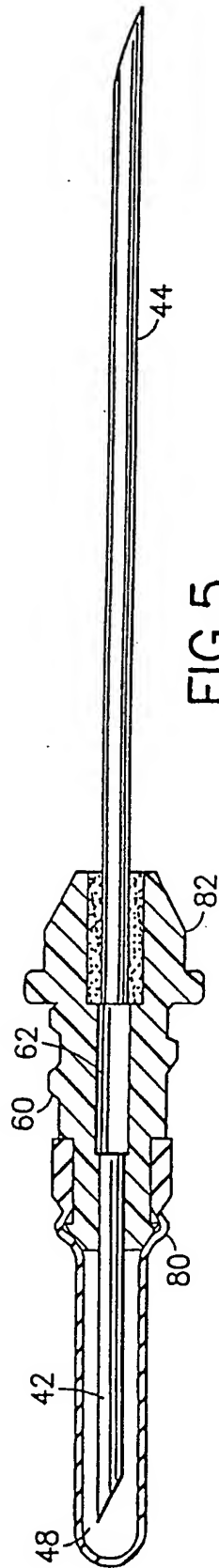
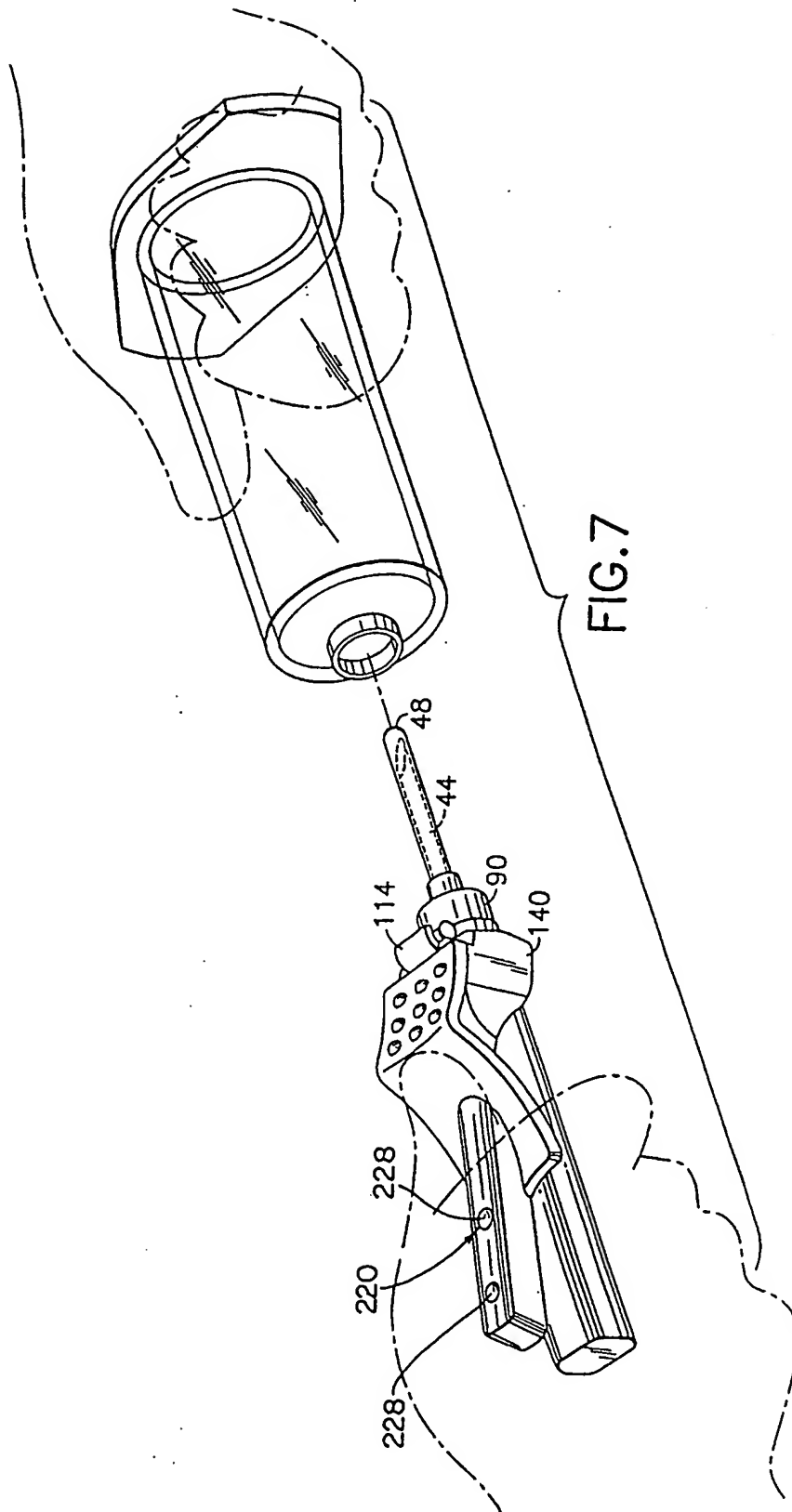


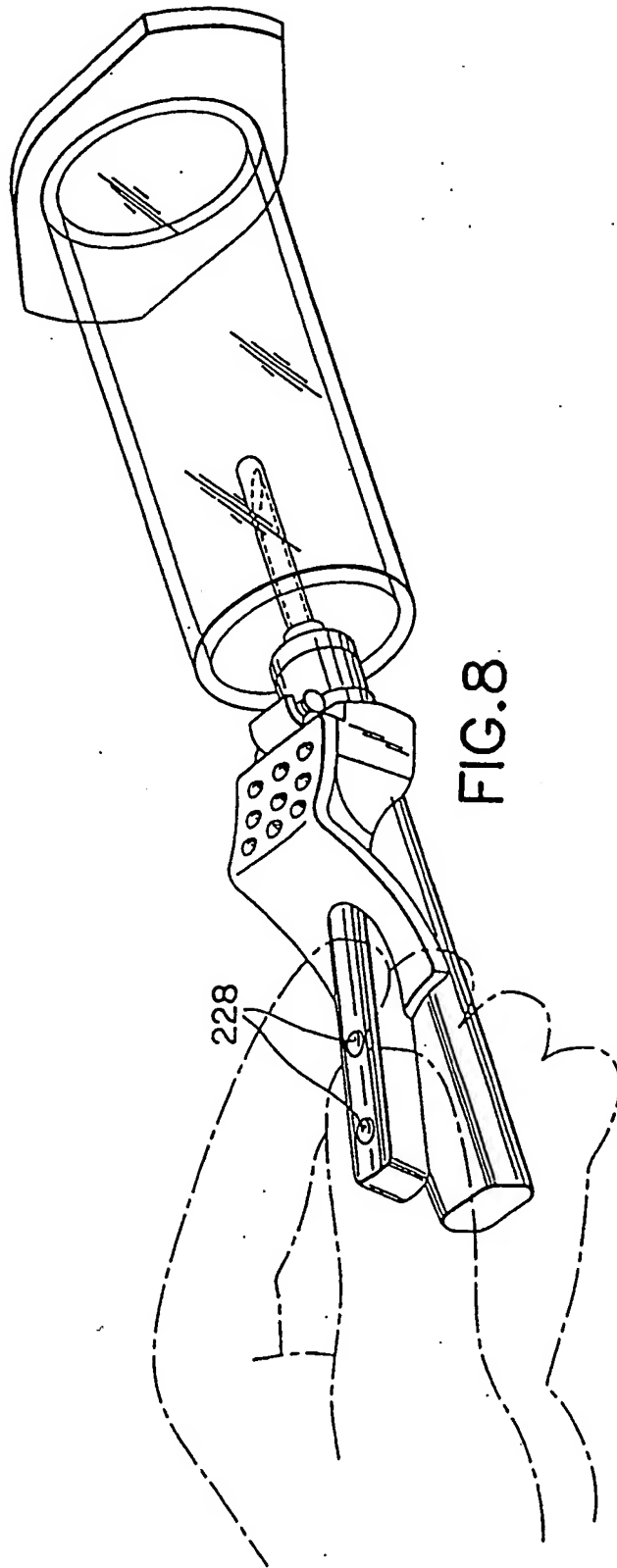
FIG. 1

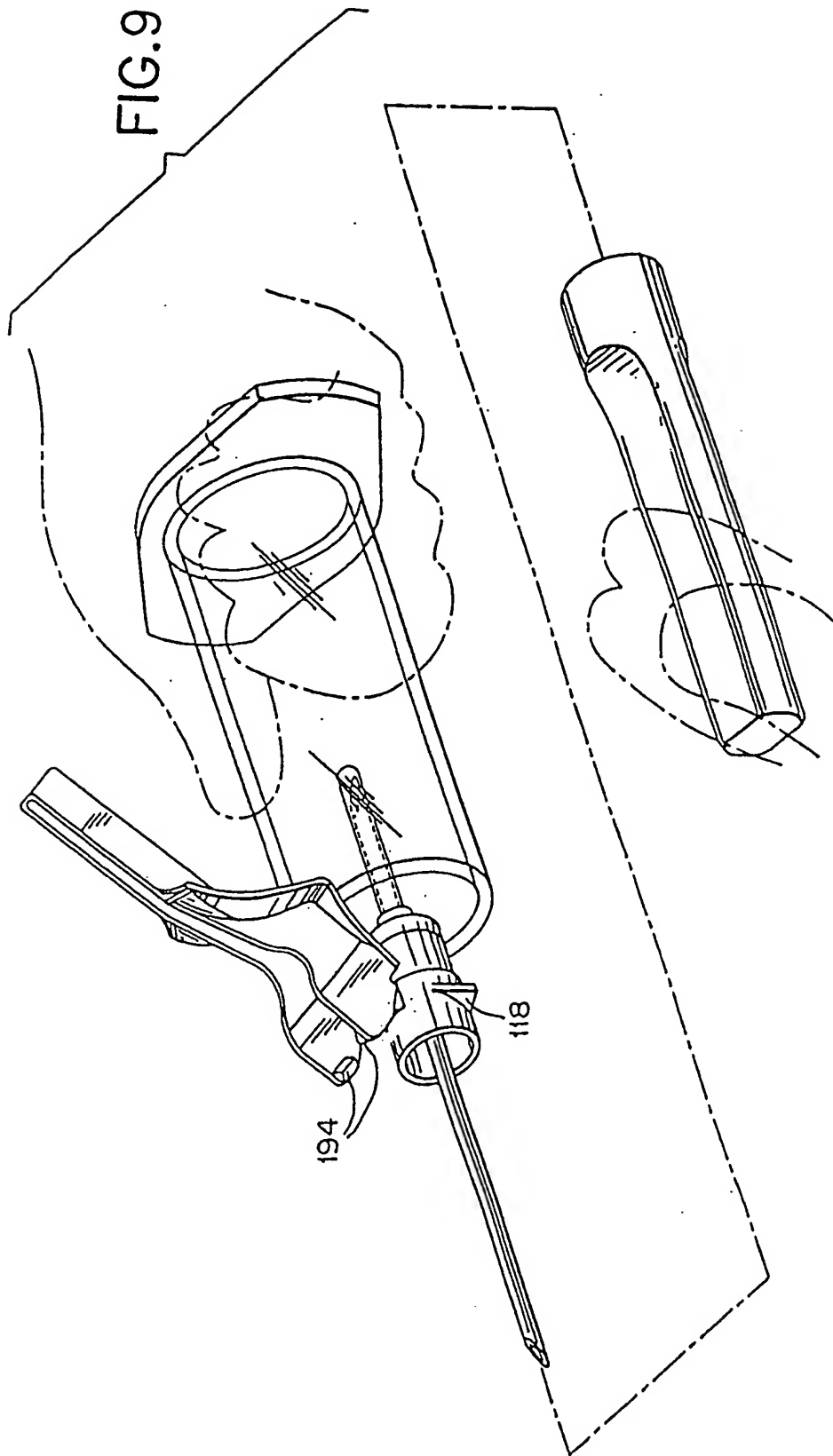












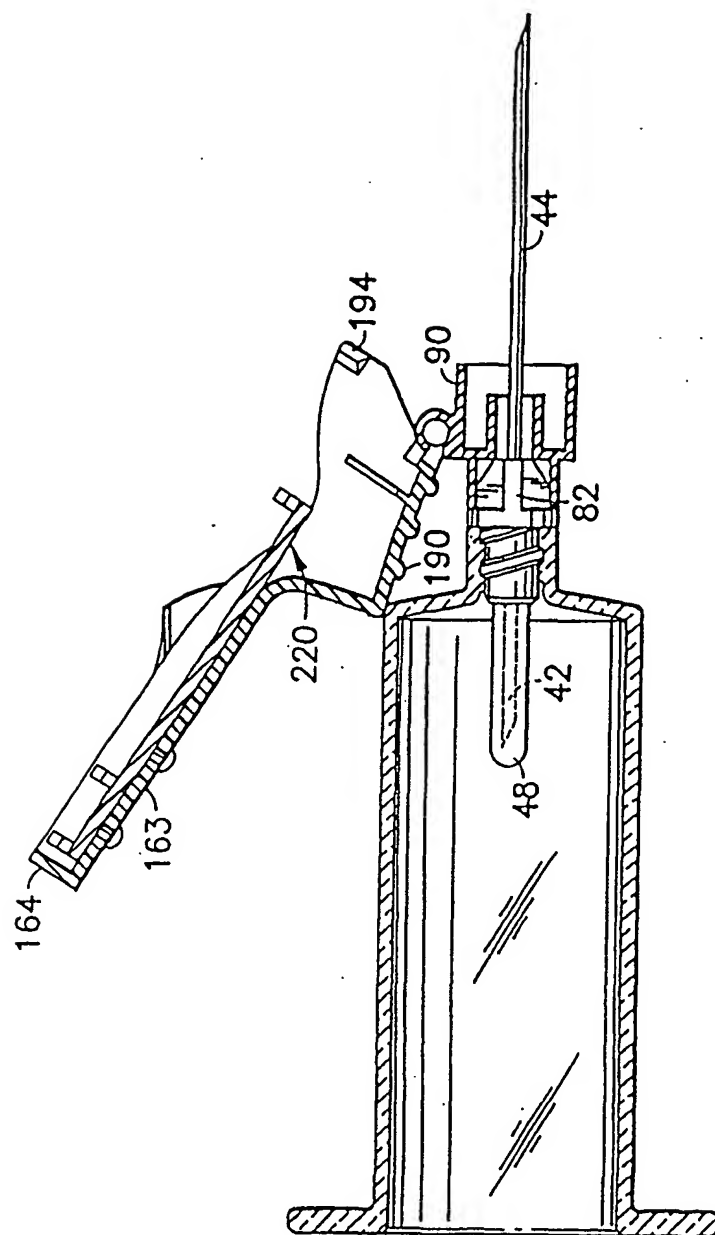
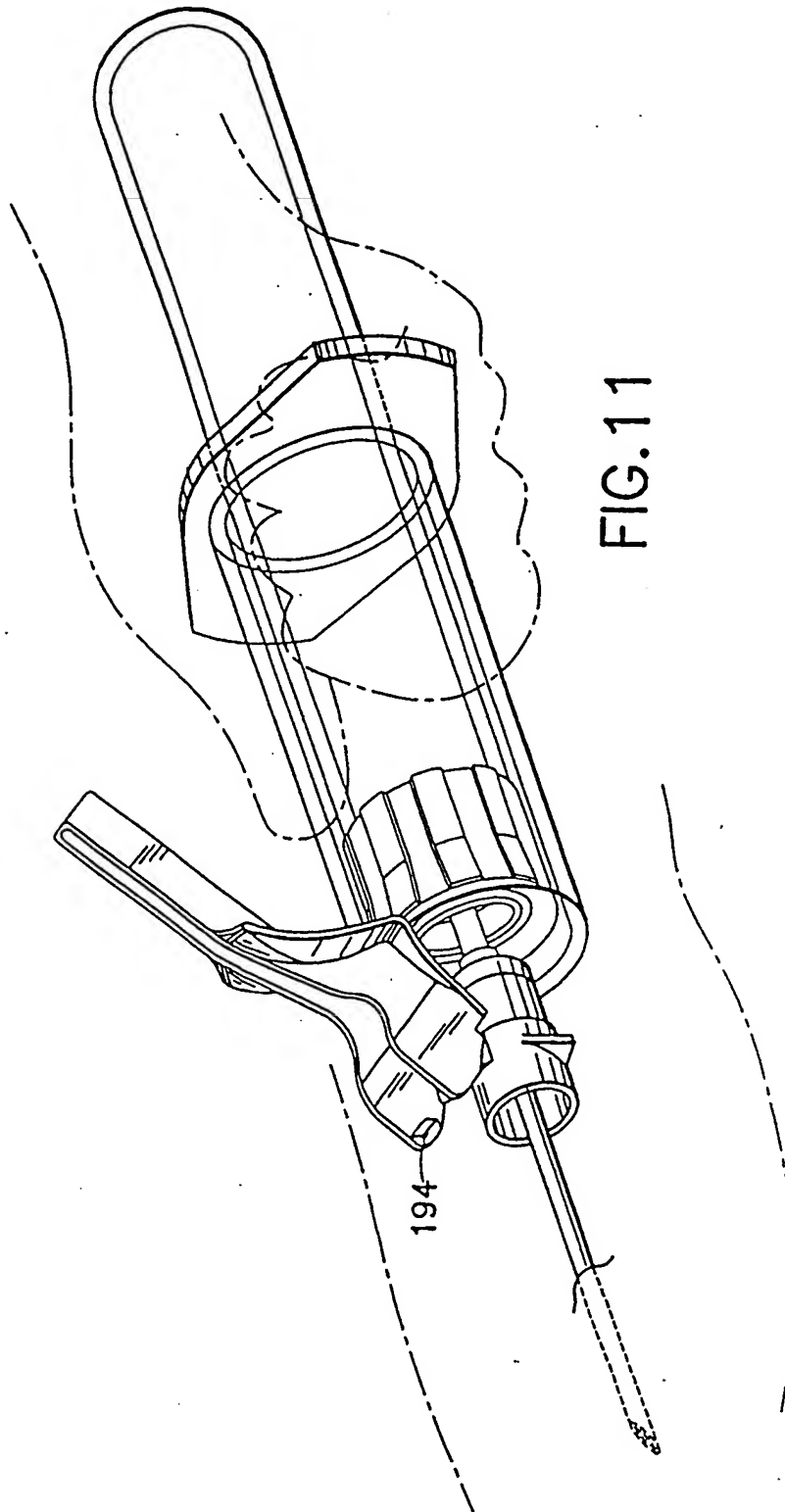
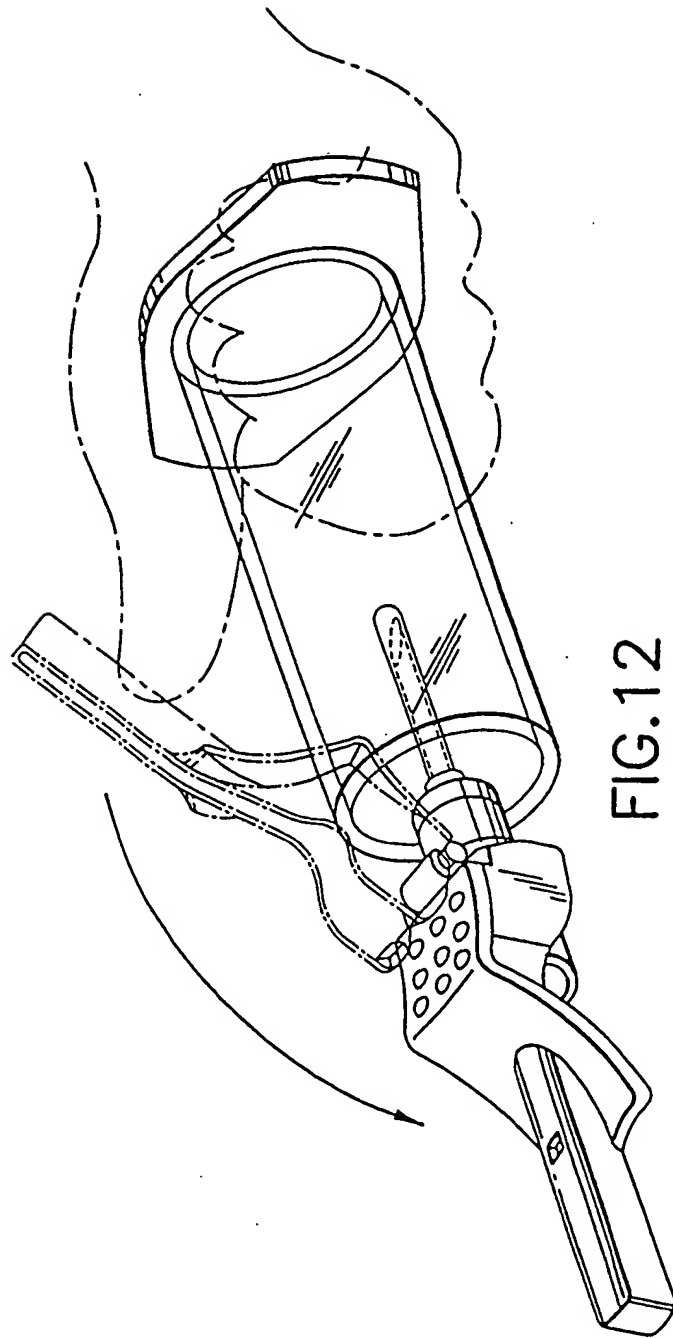


FIG.10





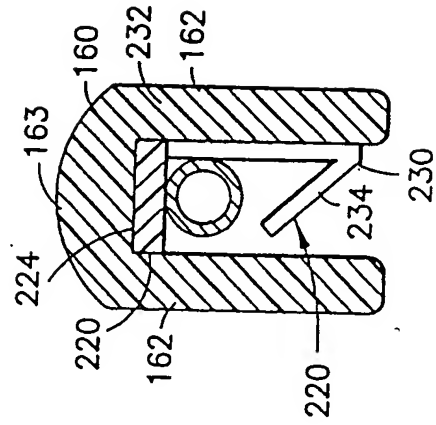
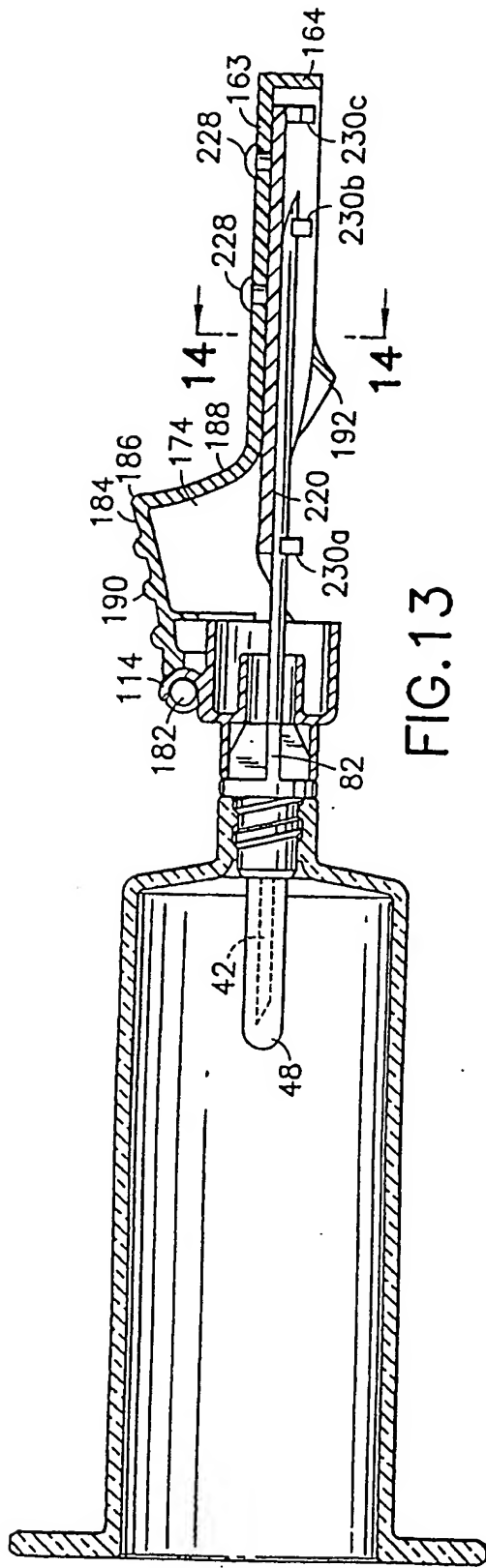


FIG. 15B

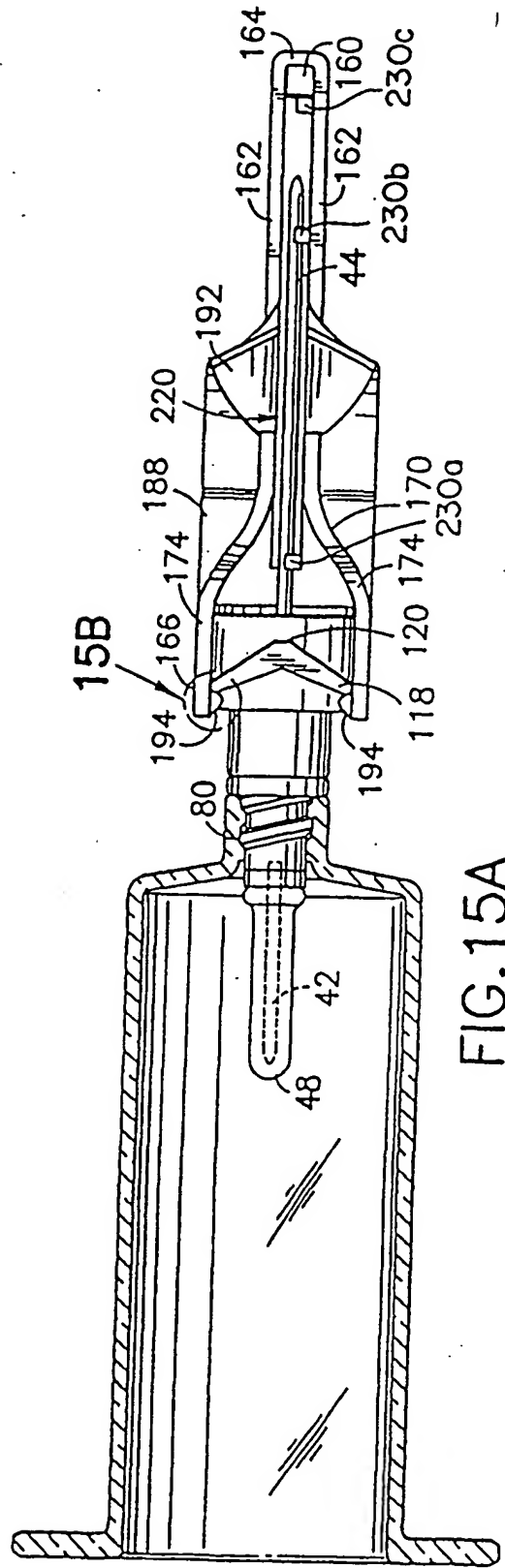
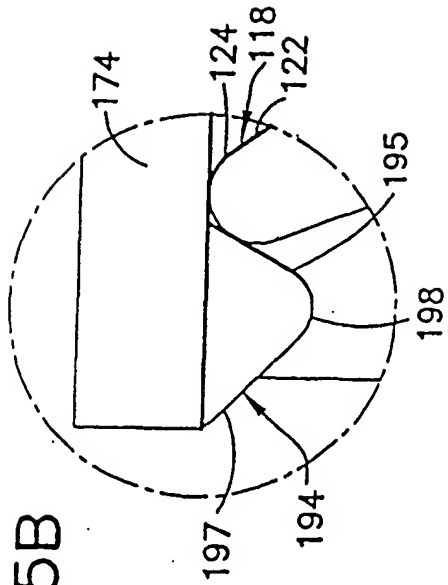


FIG. 15A

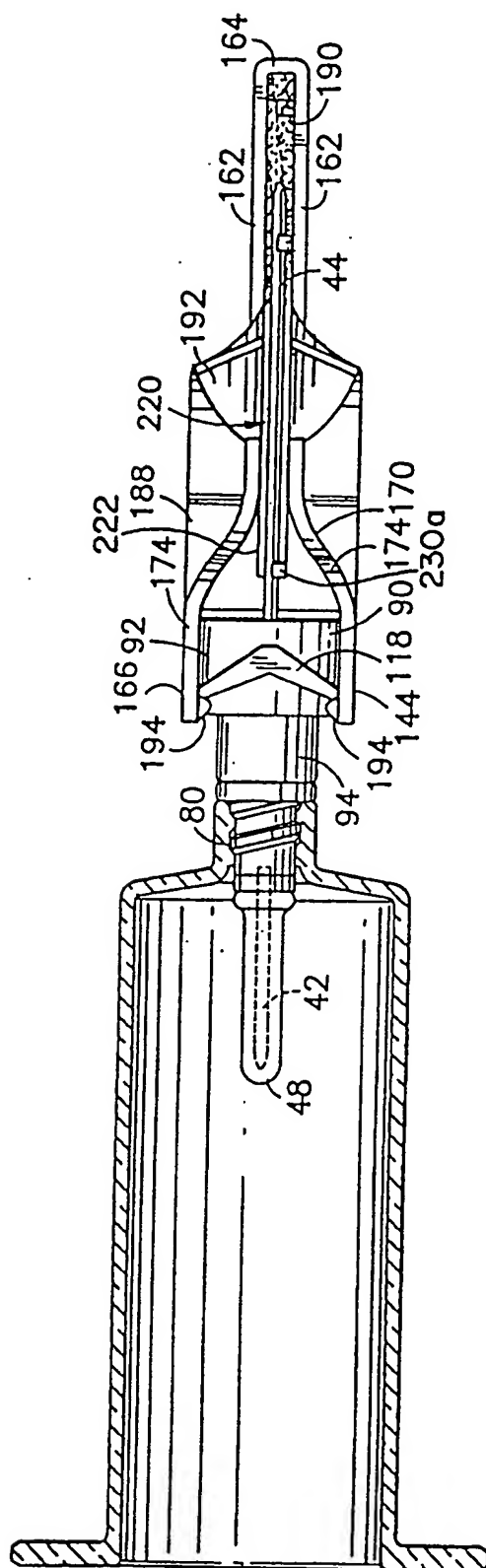
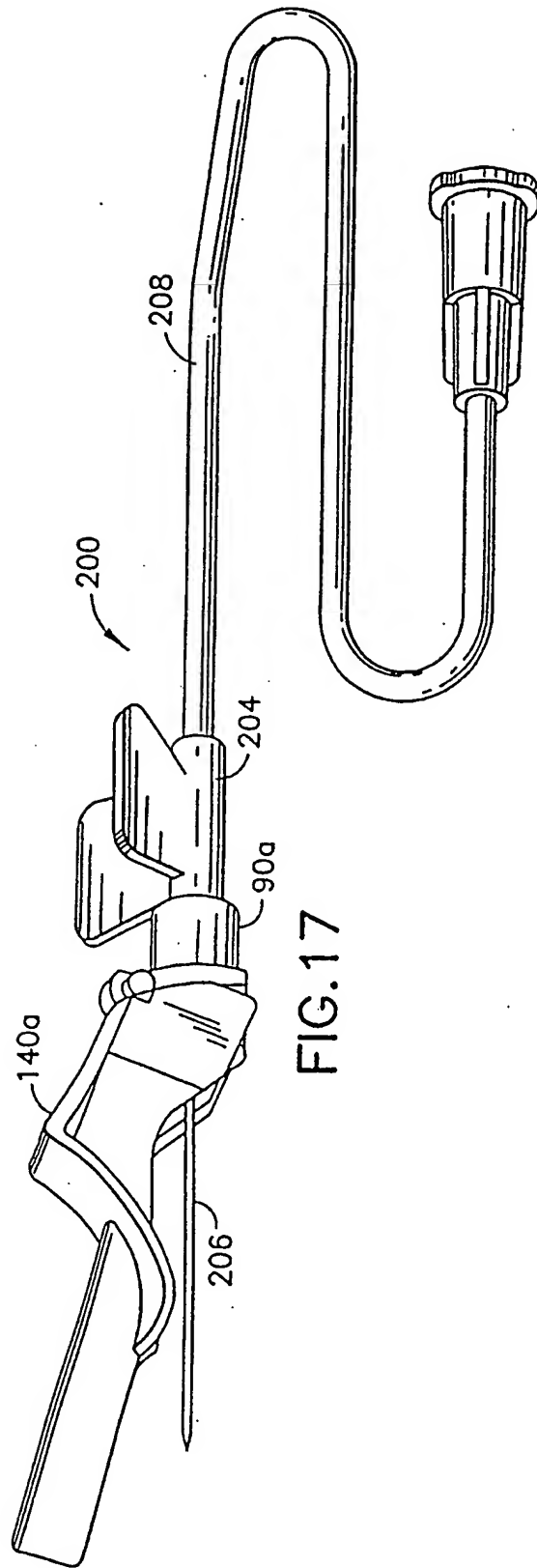


FIG.16



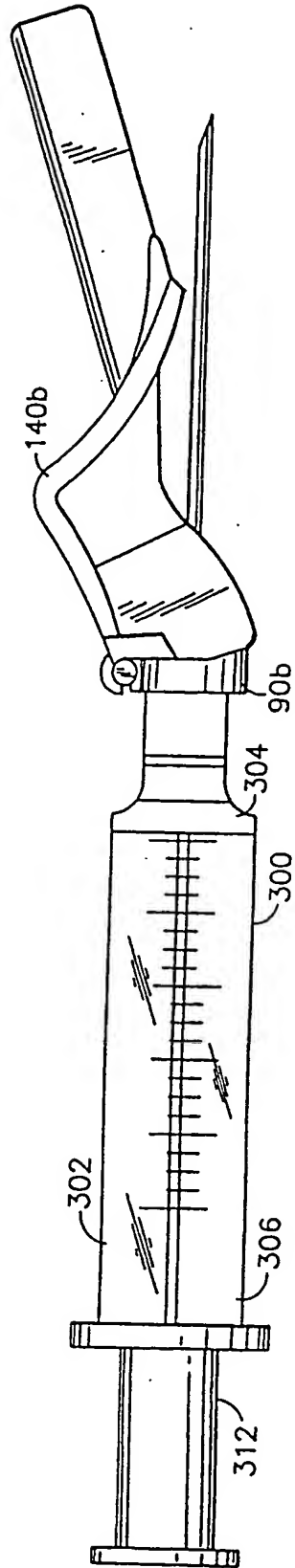
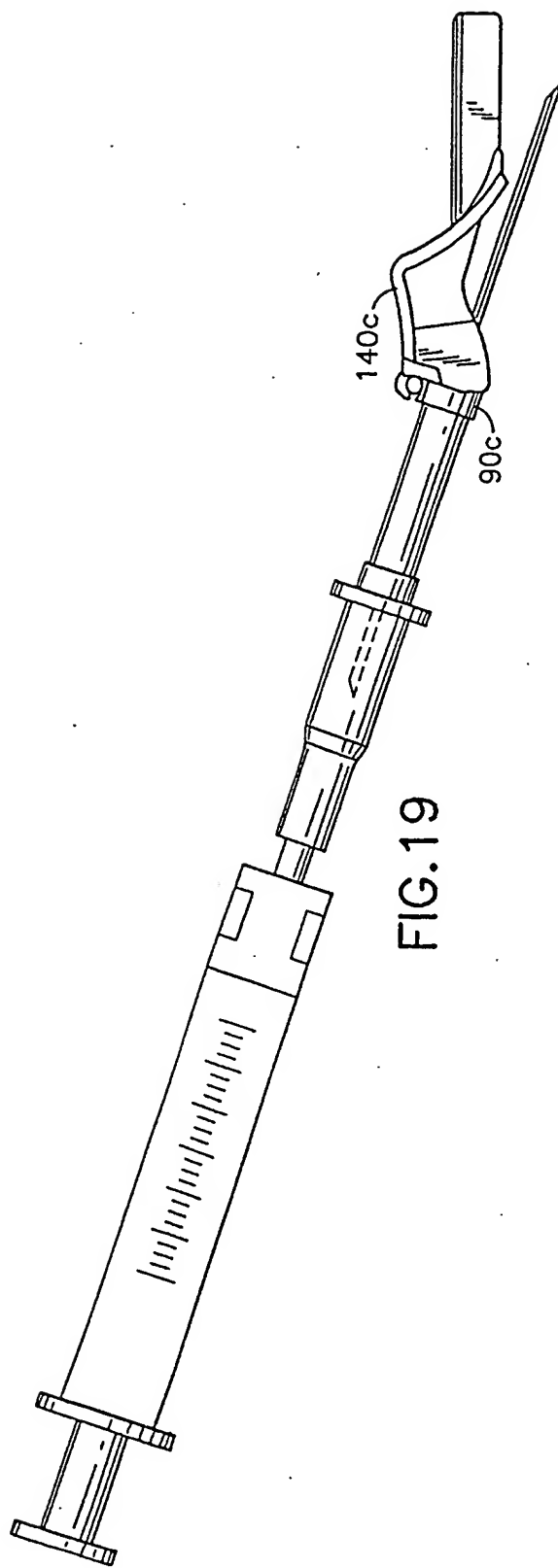


FIG.18



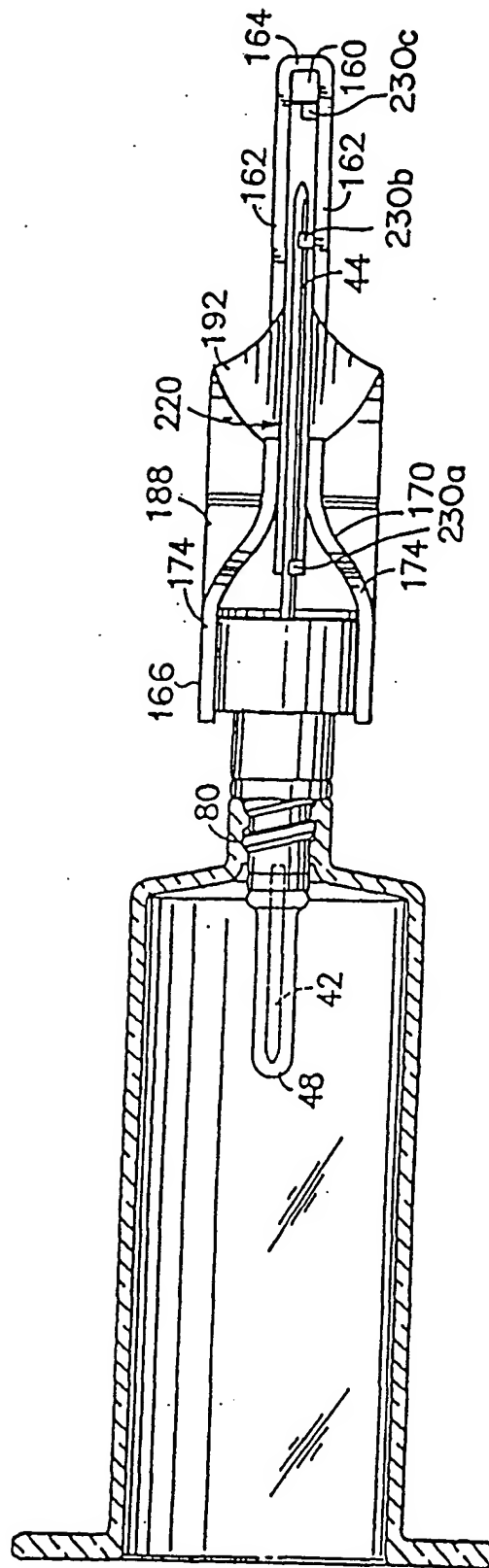
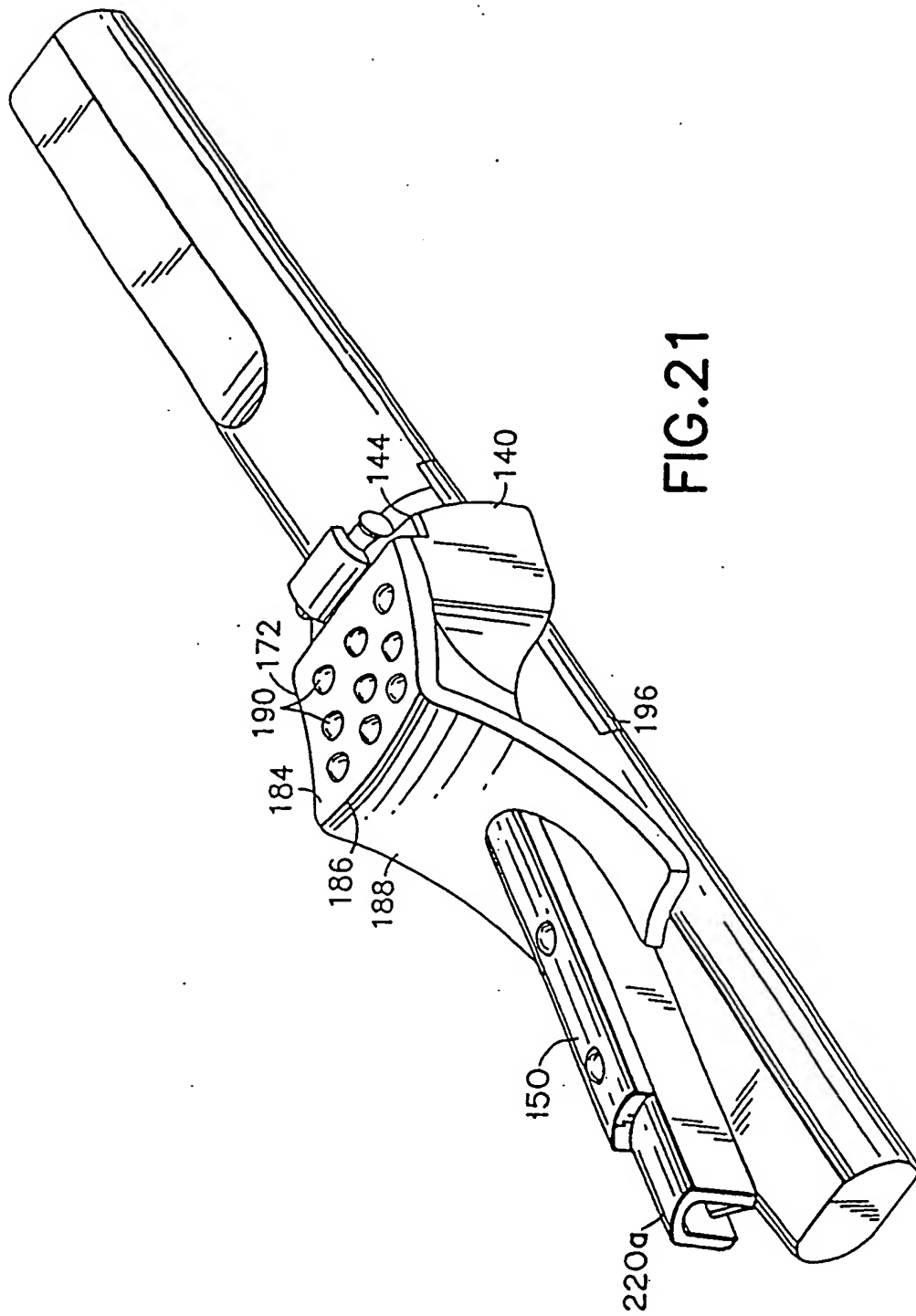
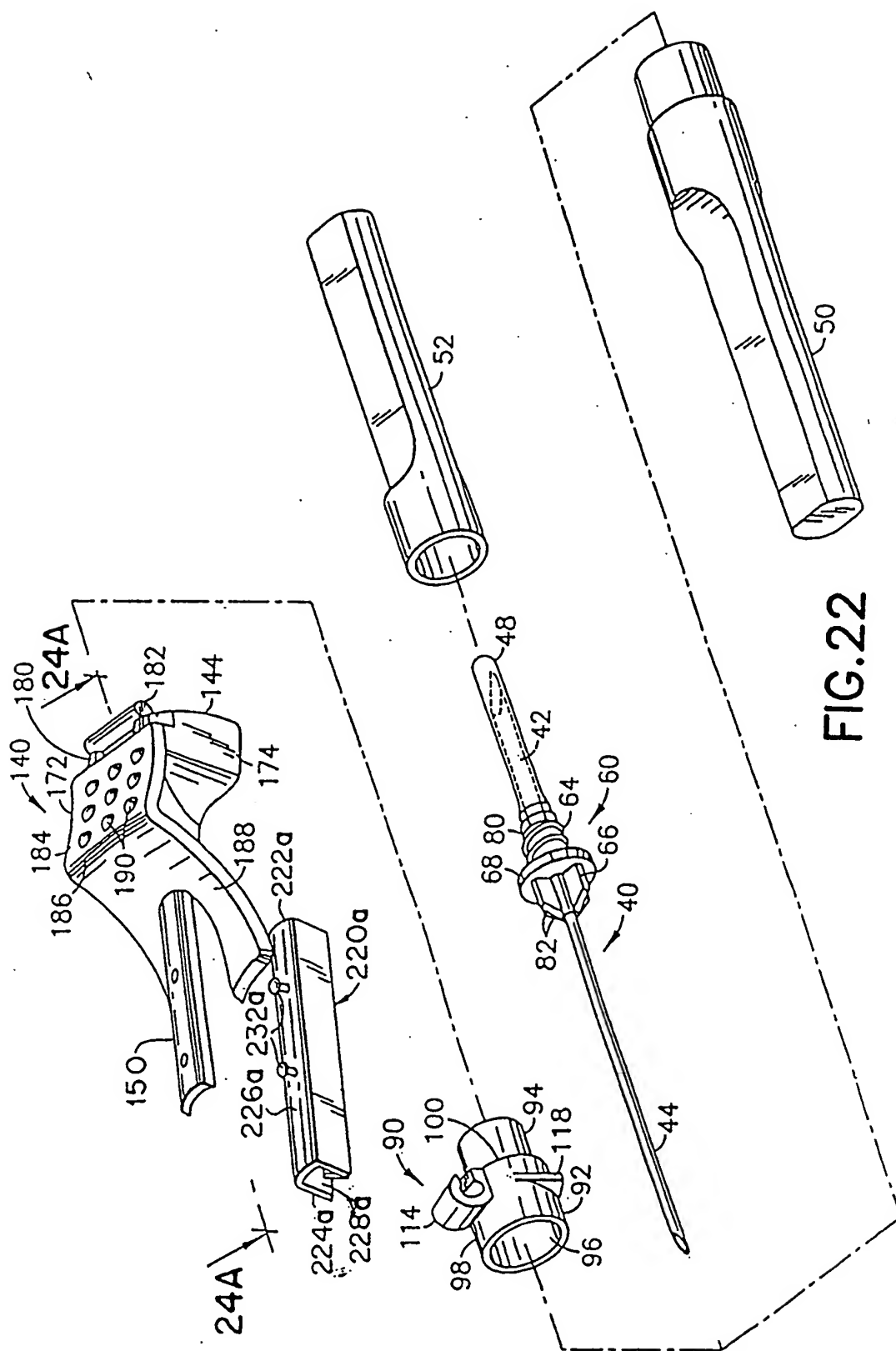


FIG. 20





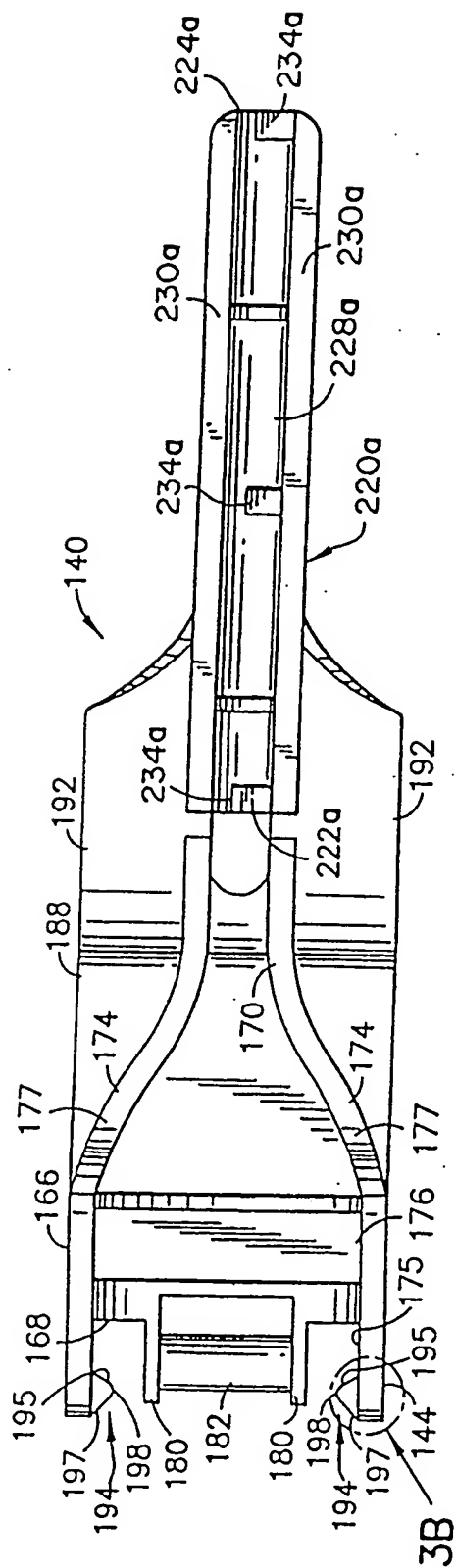


FIG. 23A

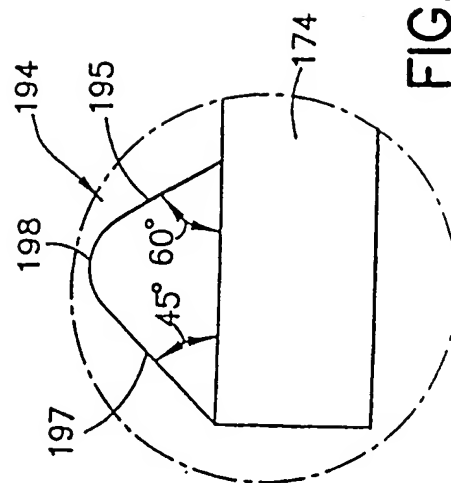
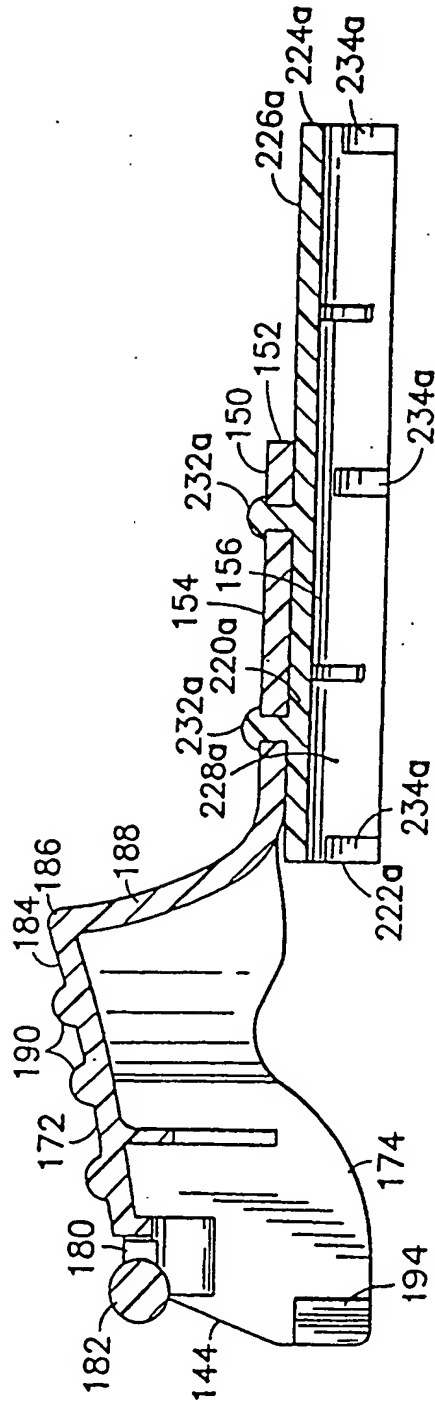


FIG. 23B

FIG. 24A



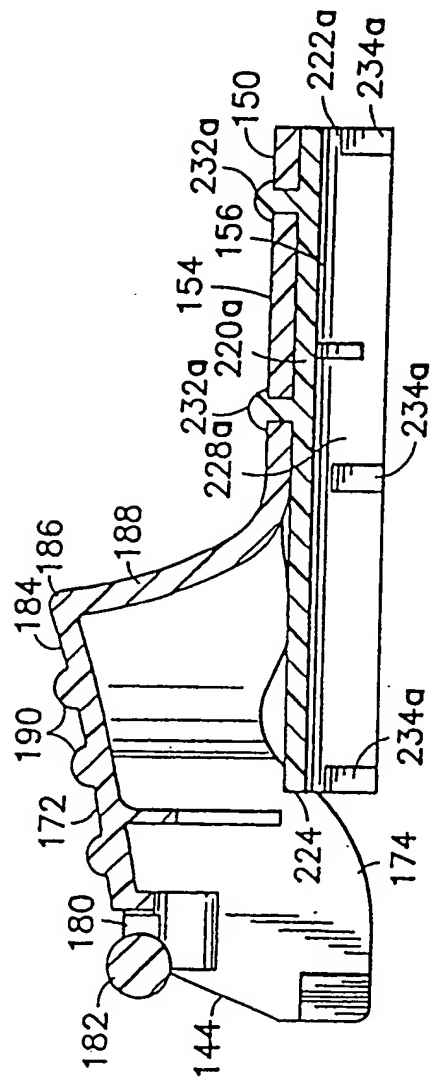
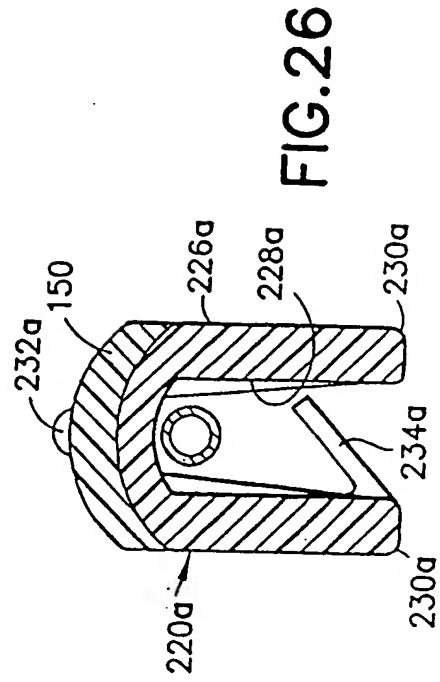
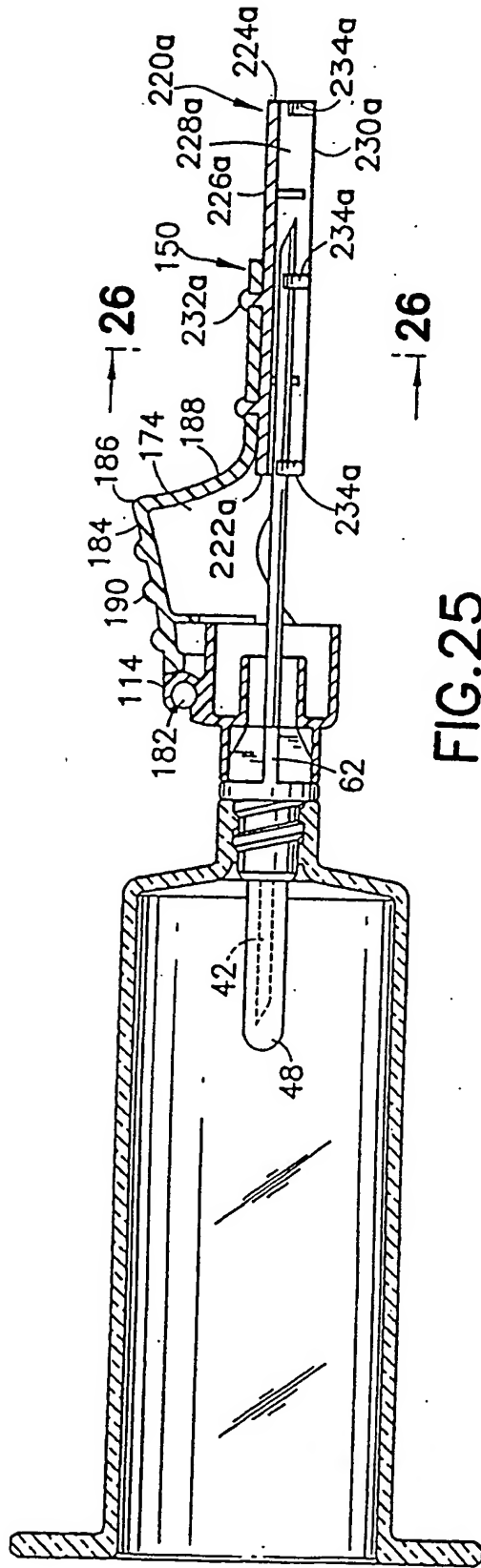


FIG. 24B



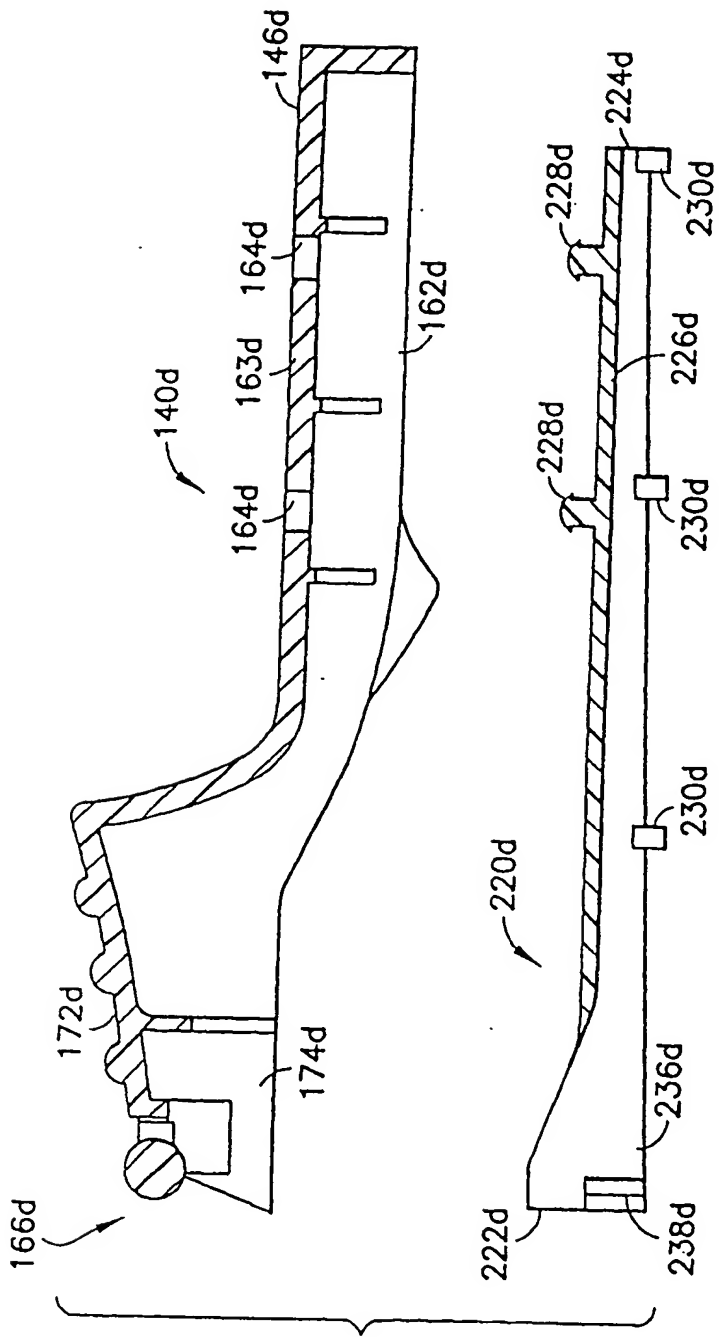


FIG. 27

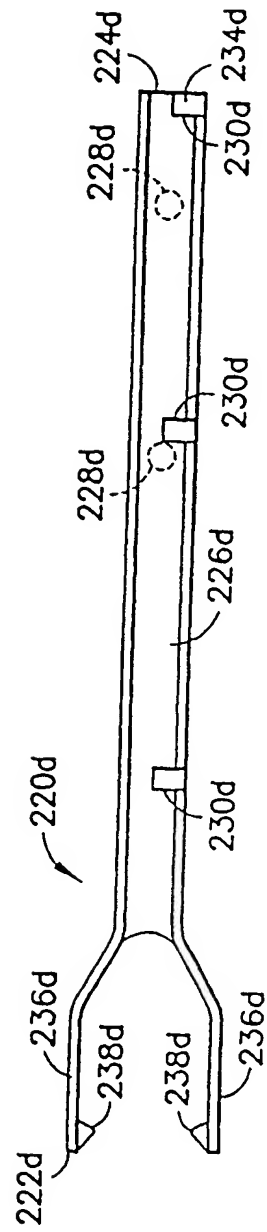


FIG. 28



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 03 01 2190

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
P,X	WO 02 098481 A (BECTON DICKINSON CO ;HWANG CHARLES G (US); NEWBY C MARK (US)) 12 December 2002 (2002-12-12) * the whole document *	1-15	A61M5/32 A61B5/14
X	US 6 298 541 B1 (BENNETT MICHAEL C ET AL) 9 October 2001 (2001-10-09) * column 1, line 55 - column 4, line 2 * * figures 1-4,6,14 *	1,7,8, 13-15 2,9,10	
A	---		
X	WO 01 78813 A (SIMS PORTEX INC) 25 October 2001 (2001-10-25) * page 2, line 5 - page 3, line 26 *	1,8 2,7,9-13	
A	---		
A	EP 0 702 973 A (BECTON DICKINSON CO) 27 March 1996 (1996-03-27) * column 16, line 10-48 * * figure 25 *	13-15	
A	---		
A	EP 0 724 890 A (BECTON DICKINSON CO) 7 August 1996 (1996-08-07) * column 7, line 39 - column 8, line 23 * * figures 8,9 *	13-15	TECHNICAL FIELDS SEARCHED (Int.Cl.7) A61M A61B
L	---		
L	US 2002/151852 A1 (BECTON DICKINSON CO) 17 October 2002 (2002-10-17) relevant document in case the priority of the present application does not hold	1-15	
L	---		
L	US 2002/156425 A1 (BECTON DICKINSON CO) 24 October 2002 (2002-10-24) relevant document in case the priority of the present application does not hold	1-15	

The present search report has been drawn up for all claims			
Place of search BERLIN		Date of completion of the search 3 September 2003	Examiner Abraham, V
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 01 2190

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

03-09-2003

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02098481	A	12-12-2002	WO 02098481 A2	12-12-2002
US 6298541	B1	09-10-2001	EP 0995455 A1	26-04-2000
			EP 0997159 A1	03-05-2000
			EP 0995456 A1	26-04-2000
			JP 2000140109 A	23-05-2000
			JP 2000084079 A	28-03-2000
			JP 2000140110 A	23-05-2000
			US 6436086 B1	20-08-2002
			US 2002141904 A1	03-10-2002
			US 6440104 B1	27-08-2002
			US 2002072715 A1	13-06-2002
WO 0178813	A	25-10-2001	AU 4987501 A	30-10-2001
			CA 2405567 A1	25-10-2001
			EP 1272241 A1	08-01-2003
			WO 0178813 A1	25-10-2001
EP 0702973	A	27-03-1996	US 5643219 A	01-07-1997
			AU 704056 B2	15-04-1999
			AU 3287195 A	04-04-1996
			BR 9504115 A	30-07-1996
			CA 2157999 A1	24-03-1996
			DE 69513357 D1	23-12-1999
			DE 69513357 T2	08-06-2000
			DE 69529179 D1	23-01-2003
			DE 69529179 T2	21-08-2003
			EP 0702973 A2	27-03-1996
			EP 0885621 A2	23-12-1998
			ES 2190039 T3	16-07-2003
			JP 8107933 A	30-04-1996
			SG 35016 A1	01-02-1997
			US 5662617 A	02-09-1997
			US 5891103 A	06-04-1999
EP 0724890	A	07-08-1996	US 5599313 A	04-02-1997
			CA 2167986 A1	04-08-1996
			DE 69603379 D1	02-09-1999
			DE 69603379 T2	06-04-2000
			EP 0724890 A1	07-08-1996
US 2002151852	A1	17-10-2002	US 6440104 B1	27-08-2002
			US 2002151853 A1	17-10-2002
			US 2002161336 A1	31-10-2002
			US 2002156425 A1	24-10-2002
			US 2002099342 A1	25-07-2002

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 03 01 2190

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

03-09-2003

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2002151852 A1		US 2002072715 A1	13-06-2002

US 2002156425 A1	24-10-2002	US 6440104 B1	27-08-2002
		US 2002151852 A1	17-10-2002
		US 2002151853 A1	17-10-2002
		US 2002161336 A1	31-10-2002
		US 2002099342 A1	25-07-2002
		US 2002072715 A1	13-06-2002

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ ~~FADED TEXT OR DRAWING~~
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.